



EVALUATION OF THE JOINT RESEARCH CENTRE'S ACTIVITIES RELATED TO REFERENCE MATERIALS

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FOREWORD BY THE DIRECTOR-GENERAL

Earlier this year I asked a panel of key personalities in the field of reference materials to prepare an assessment of the JRC's activities in this field. A few months later I am pleased to introduce the result of their work, condensed in this evaluation report, fully compliant with the panel's terms of reference.

Firstly, I consider the panel's positive assessment of the JRC's contribution to reference materials in the world as an external confirmation of the high quality of our staff and our facilities for the development, production and storage of reference materials. Secondly, I commend the panel's supplementary effort to produce a broader analysis of the context of the JRC's activities. Thanks to this, the report also offers a useful historical perspective and a deeper insight in the substance and achievements of the JRC's laboratories in Geel, which provides a common ground for further reflection.

The panel's sharp observations about prioritisation and governance and the constructive recommendations will help to address the fundamental questions for the future of the JRC in reference materials and, as indicated, indeed in the metrology community at large.

I am very grateful to Martin Milton, Beat Jeckelmann, Willy May, Danielle Roudil and Mathias Müller for making their expertise available for the benefit of the JRC and the whole reference-materials community across Europe.

We will now start exploring ways to implement their recommendations and develop a longer-term vision in the evolving broader landscape of metrology in Europe.

EXECUTIVE SUMMARY

This report presents an evaluation of the activities of the Joint Research Centre (JRC) of the European Commission in the field of reference materials. It addresses all questions in the terms of reference set for this evaluation by the JRC (shown in the annex). It distinguishes those with a peer-review character from those with a more analytical character addressing in turn the current situation and possible developments for the future. It identifies some fundamental issues for the future of the JRC's activities in this field and concludes with recommendations.

The main findings in the peer-review part of the evaluation are as follows, with the issue in question underlined:

- The reference-material activity at the European Commission's Joint Research Centre is one of the leading such programmes in the world in terms of its quality and relevance. Since this is a field where the specific demands for reference materials exceed what the leading actors can develop and supply, the JRC's contribution to the reference-material landscape in Europe and worldwide is important; the community makes good use of its products. The level of technical expertise amongst JRC staff and the extent of investment in complex equipment make it a unique capability in Europe.
- JRC's reference materials contribute to advancing the capacity to carry out accurate and comparable measurements in the EU. The latest complex reference materials fully developed by the JRC play a particular role in measurements supporting applications in health, food, the environment, engineering and the nuclear industry. They contribute to the implementation of EU legislation to different degrees, depending on the specific background. The nuclear reference materials and quality-control tools developed by the JRC also support international treaty verification.
- Many activities related to JRC's reference-materials have a significant international-co-operation component.
- The JRC's infrastructure and its unique experienced individuals constitute a European facility. Only a few National Metrology Institutes worldwide have the resources to equip their laboratories with a comparable suite of facilities.
- There are benefits in maintaining the use of the ERM trademark. In our view the availability of reference materials with a trademark plays a positive role for a certain part of the reference-materials market and their availability serves the customer.
- Although the production of reference materials by a Commission department cannot bring EU added value in itself, we recognise the value of past and future development of reference materials by the JRC. Indeed, the reference-material community elsewhere in the EU would not have been in a position to initiate the development of many of the reference materials produced by the JRC.

Regarding the more analytical questions about the intervention logic and the prioritisation in the non-nuclear reference-material activities:

- The formal intervention logic for the JRC's development and production of reference materials is not identifiable. In fact, for some applications the European Commission mandates the use of reference material in its regulation while it also produces and markets this material through the JRC. This is at odds with the "role clarity" that is expected of regulators. This triggers the question as to whether the European Commission should host a function for the development and production of reference materials and whether it would be better to transfer production, marketing and after-sales services to an arm's-length body.
- There is a lack of scrutiny at the JRC in the decisions as to which reference material is the most relevant to develop and who should produce it. This is a European-wide issue that manifests itself in many other parts of the loosely organised metrology system.

The report identifies a number of fundamental points for the future of the JRC's reference-material activities. (Since the JRC's role and duty in relation to the nuclear domain are anchored in the Euratom Treaty, they concern notably the reference-materials activities outside the nuclear domain).

- **Priority setting:** This is currently done following a "bottom-up" approach within the JRC. However, a transparent selection process and the authority of a representative selection board would serve to improve the effectiveness and the credibility of the priorities in the future.
- **A vision for the JRC's reference materials activities:** The strategic focus on reference materials around the turn of the 21st century has given way to considerably less ambition under H2020 and in the JRC's 2030 strategy. To extend the trend of JRC activities in this field, the JRC needs to renew the vision for its reference materials activities.
- **Governance within the context of the European metrology infrastructure:** The JRC contributes to the European and global metrology infrastructure with more than just reference materials, but it has no formal membership relation with the metrology community. This uncommon situation is probably not sustainable in the long run. Whether the JRC should continue to be a loosely-bound organisation within the metrology community is another question. It could be addressed in a structured discussion with the metrology community, involving the various stakeholders and the relevant departments of the European Commission.

We conclude the report by re-iterating our view that specific demands for reference materials exceed what the leading actors can develop and supply, the JRC's contribution to the reference-material landscape in Europe and worldwide is important. Hence we are of the opinion that the JRC's capacity to develop the most complex and technically challenging reference materials for the implementation of EU legislation should be maintained.

We make four recommendations for implementation by the JRC "in-house":

1. The JRC should establish a formal intervention logic for all its reference-materials activities, taking care of the possible conflict of interest between the European Commission mandating the use of reference materials in its regulations whilst also producing and marketing them.
2. Under all circumstances and as soon as possible, the JRC should establish a priority-setting body or mechanism for its reference-materials activity. The involvement of all stakeholders (inter alia, representatives from EU industry and the European Association of National Metrology Institutes: EURAMET) will give added legitimacy to the activities, and will support the development of the intervention logic.
3. The JRC should establish an external review process at the project level engaging with the stakeholder community to help prioritising reference-materials activities. As a secondary effect, such a review process may also lead to new or improved methods.
4. If further economic rationalisation of the reference-material activities is needed, the JRC could consider existing models for splitting the work such that development and production is outsourced so that the JRC can focus on the technically-demanding coordination and certification tasks.

The report discusses the possibility of developing these recommendations in the evolving broader landscape of metrology in Europe. The JRC may want to contribute to the shaping of these evolutions from inside the European Commission.

1 INTRODUCTION

This report is an evaluation of the activities of the European Commission's Joint Research Centre (JRC) concerning the development and production of reference materials. It has been written to address terms of reference issued by the JRC and given in Annex I of this report. It provides a high-level account of the work and the achievements of the JRC in the field of reference materials, an assessment of the relevance of the various parts of the JRC's reference materials programme and a list of recommendations for future developments regarding activities in the area. The report is set against the background of the recent "JRC Strategy 2030" published¹ after the panel started its work.

The scope of this evaluation encompasses all reference materials developed, produced and/or distributed by the JRC including those for nuclear analytical techniques. The latter are highly regulated and therefore subject to some separate considerations. The historical perspective of reference-materials development and production is relevant for the evaluation, but in principle the evaluation should cover the activities over the last ten years (2006-2015).

The panel had expertise that allowed it to address and assess the JRC's reference-materials activities within the context of global activities in metrology. Knowledge of the world-wide measurement system and familiarity with the JRC's contributions to the development, production and distribution of reference materials has been the basis for this evaluation.

To understand the JRC's current mandate in this area it was crucial to include a review of both the history of reference-materials work in the European Commission and the formal mandate given to its Joint Research Centre. Hence, besides hearing presentations by the JRC and visiting the reference-materials laboratories in Geel it was also necessary to analyse the official documents that provide the legal basis for the activities. The result of this analysis has been placed at the beginning of the report in Chapter 2, because it provides an important background for some observations and it reflects the dimensions into which the JRC has developed its overall long-term strategy.

To structure the work following from the terms of reference, the panel grouped the evaluative questions in two blocks: one with the first four questions, addressing the peer-review aspects of the JRC's reference-materials activities and one with the subsequent two questions addressing the rationale for the JRC's activities. Chapters 3 and 4 of the report respectively deal with these two sets of questions.

Chapter 5 of the report deals with the last evaluative question on fundamental issues for the future in light of the new organisational structure of the JRC, which followed the publication of the "JRC Strategy 2030" and came into effect before the panel completed the full draft of this report.

Finally Chapter 6 closes the report with recommendations concerning the JRC's activities on reference materials.

2 HISTORICAL BACKGROUND OF REFERENCE MATERIALS AT THE JRC

In 1960 the JRC started a Central Bureau for Nuclear Measurements in Geel (Belgium) as part of the Commission's tasks under the Euratom Treaty. The Bureau had the task of measuring physical constants extremely precisely, for which it had a Van de Graaff accelerator and a linear accelerator at its disposal. Over the years this core of nuclear metrology has grown into a well-established capability for the development and production of certified reference materials (CRMs).

The first activities of the European Commission in the field of metrology started in 1973, when it established the Bureau Communautaire de Références (BCR), i.e. the Community Bureau of References. In fact the "bureau" was an indirect research² action programme to provide measurement services and standards across many

sectors of industry with the mandate to organise interlaboratory studies and to certify materials using existing laboratories in the Member States. More than a decade later, in 1987, the BCR became part of the second European Community Framework Programme (FP) for Research, by the Commission's DG XII predecessor of today's DG Research and Innovation. Under the Third Framework Programme (FP3, 1990 - 1994) the BCR was reborn as the specific programme "Measurements and Testing" to become the programme "Standards, Measurements and Testing" under the Fourth Framework Programme³ (FP4, 1994 - 1998).

With its metrology competence and experience in the nuclear area the JRC institute in Geel became involved in the BCR programme off and on. FP3

Box 1. Reference materials in the Council decision on JRC's specific programme in the Fourth Framework Programme¹ (1995-1998)

Line 5: Measurements and testing

Pre-normative research on reference materials and pre-normative and normative research on reference measurements, in particular in the following sectors:

- preparation, characterization and certification of high-quality reference materials. International intercomparison exercises will be used to ensure adequate quality assurance and to facilitate harmonization,*
- establishment of a common scientific basis for the chemical reference measurements,*
- measurements and evaluation of basic data, improvement of their quality and accuracy using the experimental installations available and by making use of European and international collaboration, in particular through networks.*

The distribution of reference materials produced within a Community framework is assured by the Institute for Reference Materials and Measurements (IRMM). The results achieved by IRMM in establishing extremely accurate measurements have won it recognition as a reference centre. Intercalibration campaigns conducted by the IRMM among the network of all interested laboratories in the Community will provide each laboratory with an impartial and reliable evaluation of the quality of its own measurements. This activity will be extended on request to any third country laboratory, on payment of a fair fee.

Line 10: Agriculture and fisheries [...]:

- The elaboration of methodologies for reference measurements and the preparation of reference materials necessary for the quality control of food products are another impartial contribution of the JRC to the European agricultural policy.*

mentioned this as “*the JRC will contribute ... via work on advanced materials which gives priority to the pre-normative aspect, the preparation of nuclear and non-nuclear reference materials, the acquisition of reference data and the validation of certain reference techniques*”. At the time the diversification of the JRC⁴ was in full swing while Council and Parliament encouraged the JRC to “*compete progressively for the funds available through indirect action and for scientific and technical support activities which are suited to a competitive approach*” (see ref. 3).

In 1994 an exchange of letters within the Commission’s DG XII/JRC confirmed an arrangement that the JRC would “take the responsibility for producing and recertifying new

batches of CRMs, receiving the right to determine both the price and sales policy for the BCR-CRMs”. In the spirit of these developments the name of the JRC’s institute had just been changed into the Institute for Reference Materials and Measurement (IRMM). All this was formalised in the subsequent Council decision of the JRC’s specific programme in FP4 (see Box 1).

Through these acts the JRC became a visible actor in the field of reference materials beyond the nuclear domain with a formal task in measurements and testing, i.e. pre-normative research and taking care of the distribution, storage and stability monitoring of reference materials.

Box 2. Reference materials in the Council decision on JRC's specific programme in the Fifth Framework Programme¹ (1998-2002)

- *development, production and certification of reference materials for clinical diagnostics and validation of testing instruments,*
- *contribution to the establishment of sound and feasible limits for pollutants, the production of commonly accepted reference materials and measurements for monitoring them...*
- *support to the international harmonisation of pollution-monitoring techniques; development and production of reference materials and measurements in different materials (e.g. soil, water, air, biota, etc.) for pollution control,*
- *development and production of certified reference materials and development of reference methods for securing the quality of agricultural products (e.g. nutritional components, trace contaminants in raw materials, etc.).*
- *the characterisation, production, storage, stability testing and international distribution of Community Bureau of References (BCR) certified reference materials is underpinning many of the activities performed by JRC in support of different policies (environment, consumer protection, health, industrial competitiveness, etc.);*
- *production of industrial certified reference materials particularly when urgent intervention is needed or when stocks need to be replaced,*
- *development and performance of primary isotopic measurements; production of isotopic reference materials and establishment of a virtual institute of primary isotopic measurements with national measurement institutes, for transboundary comparability of chemical measurements, to support accreditation bodies and quality assurance systems and to realise traceability of chemical measurements to common references; support to Member States in building up their own metrology systems;*
- *development and validation of analytical reference methods for elements and their chemical forms, radionuclides and organic constituents; research on radionuclide metrology for the preparation of primary standards, equipment calibrations and determination of trace elements,*
- *pre-normative research and support to the development of measurement and testing standards for materials in emerging technologies such as nanotechnologies*

In the subsequent FP5 and the FP6 the Council decision for the JRC's specific programmes gave abundant room to reference materials specifying long lists of activities as in Box 2.

The main text of the FP6 includes three horizontal activities for the JRC one of which is "reference materials and measurements: the Community reference bureau (BCR) and certified reference materials; validation and qualification of chemical and physical measurement methods". Its annex

"Scientific and technological objectives, broad lines of the activities and priorities" maintains a prominent place for reference materials in the JRC (see Box 3).

The Seventh Framework Programme (2007-2013) no longer mentions reference materials in the main text of the programme, but still gave a broad description in the JRC specific programme under the headings "Competitiveness and Innovation", and "Life Sciences and Bio-technology" (see Box 4).

Box 3. Reference materials section in the Council decision on the JRC's specific programme in the Sixth Framework Programme¹ (2002-2006)

Reference materials and measurements

Recognition of standards and measurements in products is an important component for the implementation of Community policies related to consumer safety, free trade, competitiveness of European industry and external relations. The JRC will further support the existing or developing European metrological infrastructure to produce results of demonstrated quality, develop specific reference measurements, produce certified reference materials (CRMs) to improve their global acceptance, organise international measurement evaluation programmes and will establish trans-national databases in support to EU policies. Throughout the JRC's work programme, agreed reference methods and materials are required, whether in environment, food safety, public health or the nuclear industry. In addition to work described in the previous sections, the JRC plans to support the creation of a European Certified Reference Material system. This will put the JRC in a position to provide sound advice to Commission services where applicable to EU legislation and practice. The activities will cover:

- BCR and industrial certified reference materials

This activity concerns developing concepts and techniques for the production and certification of reference materials to improve their global acceptance under the EU-US Mutual Recognition Agreement, where the JRC advises DG TRADE. The JRC will concentrate on production of BCRs [reference materials] and new CRMs for control of industrial processes and products. As support to

DG RTD, the JRC will, where feasible, extend its responsibility for storage and distribution of BCR to the management of the production and certification of new CRMs from indirect actions. Nuclear reference materials used for safeguards and nuclear materials accountancy will be expanded to the environment.

- Metrology in chemistry and physics

The information generated by studying the interactions of neutrons with matter is fundamental to many applications areas. Infrastructures will be maintained to investigate basic metrology in physics in a systematic manner over a wide energy range, emphasising its relevance for training. The radionuclide metrology activity provides support to food, chemical and environmental safety. The JRC will continue to represent the Commission in international bodies responsible for the development of a world-wide chemical measurement system. Strategic tasks will include the development of primary measurement techniques, the production and certification of isotopic reference materials and organisation of International Measurement Evaluation Programmes. Topics depend on EU policy requirements and evaluations rely heavily on the participation of numerous laboratories, especially those which have a reference role to play in their sector or region. Through the establishment of networks (PECOMet-Network and MetMED) support will be provided to Candidate Countries and Mediterranean countries to build up a structured measurement system in chemistry

Box 4. Reference materials in the Council decision on the JRC's specific programme in the Seventh Framework Programme¹ (2007-2013)

Competitiveness and Innovation

Fostering EU competitiveness, transparency of internal market and trade will be pursued by the production and dissemination of internationally accepted references and the promotion of a common European measurement system. Comparability of measurement results will be fostered through the provision of quality assurance tools like reference materials, reference measurements, validated methods and data in a broad range of policy related areas such as:

- *safety of chemicals and products including cosmetics, through the development of a system of reference for integrated chemical risk assessment and by S/T support to the chemicals legislation including support (training) to the preparation of European Chemicals Agency (ECA),*
- *alternative (non-animal) testing approaches and intelligent testing strategies,*
- *food safety, quality and authenticity; feed safety; bio-technology,*
- *eEnergy (cleaner and renewable energy sources and carriers),*
- *security and protection of the citizen,*
- *environment and health.*

This reference work will be pursued in close cooperation with Member State institutions, international standardisation bodies (ISO, CEN, Codex Alimentarius, AOAC), regulatory authorities and industry. The JRC [will] maintain a role as Community Reference Laboratory (CRL) in the areas of genetically modified food and feed, food contact materials and feed additives and take up a role as CRL in further related fields of its competence.

Support to competitiveness will also be provided through activities such as support to the setting up and maintenance of European standards such as Eurocodes, Euronorms, IEC, ISO norms and European Reference Materials.

Life Sciences and Bio-technology

Life sciences and bio-technology are pertinent to many policy areas where they can significantly contribute to the Community objectives. This potential is broadly recognised in health, agriculture, food, environment and other sectors where applications are being rapidly developed. The provision of reference materials and validated methods requires access to and control of a broad range of advanced bio-technological instruments. In the context of its collaboration with competent national organisations, the JRC will further develop its competencies in this area in view of the legislative and regulatory context.

The current Framework Programme Horizon 2020 no longer has different specific programmes and the JRC activities are spelled out in general terms. Under the heading “Broad lines of activities” for the JRC it refers to reference materials as an area of competence and something to focus on regarding industrial leadership (see Box 5).

Hence H2020 explicitly mentions “reference materials” as a key competence area and the development of reference materials is mentioned only under “industrial leadership” as a contribution

to European competitiveness. Reference materials are not explicitly mentioned under “societal challenges” as contribution in areas such as food, feed and consumer products; environment and health; health-related diagnostic and screening practices; and nutrition and diets.

The latest implementing decision⁵ of the European Commission on the JRC’s multi-annual (2016-2017) work programme⁶ mentions reference materials lightly and scattered under different headings:

Box 5. Reference materials in the Regulation establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)¹

The JRC's key competence areas will be energy, transport, environment and climate change, agriculture and food security, health and consumer protection, information and communication technologies, reference materials, and safety and security (including nuclear safety and security in the Euratom programme). The JRC activities in these areas will be conducted taking into account relevant initiatives at the level of regions, Member States or the Union, within the perspective of shaping the ERA.

The JRC shall focus on:

“Industrial leadership”

Contribute to European competitiveness through support to the standardisation process and standards with pre-normative research, development of reference materials and measurements, and harmonisation of methodologies in five focal areas (energy; transport; the flagship initiative 'Digital Agenda for Europe'; security and safety; consumer protection)...

“Protecting and enhancing our natural capital”, subheading “Freshwaters and the marine environment”: Develop standards and reference materials for water pollutants for all freshwaters and marine waters;

“Protection from environment-related risks to human health and wellbeing” subheading “Chemicals and nanomaterials”: Develop methodologies, standards (e.g. at CEN/ISO) and reference materials for nanomaterials...;

“Food safety”: Run the six EU reference laboratories, produce certified reference materials, develop harmonised/validated methods and new analytical tools;

“Promote excellence in the nuclear science base for standardisation”: Support to standardisation and harmonisation of radiological measurement methods in the EU and collaboration with key partner countries and international organisations (IAEA, OECD-NEA) in the field, by providing state-of-the-art nuclear reference materials, measurements and data and by developing and implementing relevant test standards, databases and assessment tools.

The new “JRC Strategy 2030”, which was published after the panel started its work, mentions reference materials as part of today's activities. “It [the JRC]

carries out pre-normative research and develops standards, harmonised methodologies, reference measurements and materials, which are critical for innovation and the internal market, as well as environmental protection and consumer protection. All of this is essential for the uniform implementation of EU legislation, especially for establishing regulatory limits.”

In the drafting phase of this evaluation report we learned that the Commission decided on a new organisational structure for the JRC with four departments respectively for strategy and coordination, for general support, for knowledge production and for knowledge management. This new structure means a break with the past when the JRC had seven institutes accommodated at five sites in five different Member States. It also means that the JRC Institute for Reference Materials and Measurements (IRMM) no longer exists as a named entity. Nevertheless, all reference-materials activities remain physically located in the laboratories in Geel. In the new organisational structure all nuclear reference-materials activities fall under the Directorate for Nuclear Safety and Security in the Unit “Standards for Nuclear Safety, Security and Safeguards”, while all other reference materials activities fall under the Directorate for Health, Consumers and Reference Materials in the Unit “Reference Materials”.

All these organisational developments are driven by the full spectrum of JRC activities in the context of its position as a Commission department. They obviously have no connection with our findings, but they may have an effect on the JRC's contribution to the field. The disappearance of the name "IRMM" reduces the visibility of JRC's activities in reference materials.

Nevertheless, the reference-materials catalogues of the JRC now counts more than 800 different

materials. Around 700 materials are related to environmental analysis, the analysis of food and feeding stuff, clinical chemistry, industrial applications and isotopic measurements, or certified for physical properties. Another 100 are certified reference materials for nuclear safeguards. The JRC clearly is an important provider of reference materials in its field of specialisation.

3 ACTIVITIES AND ACHIEVEMENTS

To respond to the questions about the JRC's activities and achievements we requested that JRC prepare key elements to answer the first set of evaluative questions. The sections of this chapter are based on the JRC's response (quotes in italics), critiqued and validated by the panel.

3.1 ROLE AND COMPETENCE OF THE JRC

In which sub-areas of this field does the JRC have a unique role and/or is the use of its competence essential?

The "unique role" of the JRC may refer to the uniqueness of its institutional role, i.e., its legal mandate in reference materials. It may also refer to the uniqueness of its technical and economic role in the development and production of reference materials. Similarly "competence" also has two meanings, on the one hand the JRC's institutional remit and on the other hand the proficiency of the JRC.

Considering the peer-review character of this chapter institutional roles and considerations are kept for the next chapters. Here our response focuses on the uniqueness in techno-economic and proficiency sense.

The reference-material activity at the JRC is one of the leading such programmes in the world in terms of its quality and relevance. The reference materials divisions in the JRC work according to the ISO norms, respect the relevant ISO guides and are highly performant with reference materials in the specialised areas in which they are active. In fact, the reputation of its reference-materials institute has sometimes taken mythical proportions⁷:

"The Institute for Reference Materials and Measurements (IRMM), a research establishment that, for more than fifty years, has produced the physical referents of European Union law"

"IRMM is the agency tasked by European authorities with the fabrication of dependably

constant versions of the entities mentioned in EU legislation".

Although these quotes slightly overstate the role, the quality of JRC's reference materials is world class in the eyes of its peers and generally praised in the satisfaction surveys that the JRC organises on a regular basis amongst customers that purchase its CRMs directly from the JRC or via authorised distributors. The global reference-materials community makes good use of the JRC's products.

Since this is a field where the specific demands for reference materials exceed what the leading actors can develop and supply, the JRC's contribution to the reference-material landscape in Europe and worldwide is welcome; the community makes good use of its products. Hence, the JRC can claim a unique role for all complex CRMs that it produces. This is to a large extent inherent to the restricted global capacity in this field that functions as a natural brake to duplication amongst reference-material producers.

The level of technical expertise amongst JRC staff and the extent of investment in complex equipment make it a unique capability in Europe.

3.2 MERITS OF JRC'S REFERENCE MATERIALS

3.2.1 IMPLEMENTATION OF EU LEGISLATION

To what extent do the JRC's reference-materials activities contribute to the implementation of EU legislation?

3.2.1.1 Reference materials designed for food/feed safety or labelling

We received the following examples of legislation that is implemented using reference materials designed (and produced) by the JRC for food/feed safety or labelling:

- *REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, which provides a general framework for official*

controls performed by the Member States to verify compliance with feed and food law, animal health and animal welfare. This is organised via EU reference laboratories (EURLs) and national reference laboratories (NRLs). The JRC supports the domains for which it is the designated EURL, with reference materials for proficiency testing exercises and CRMs for calibration/trueness evaluations;

- *GMO: REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and COMMISSION REGULATION (EU) No 619/2011 requiring the availability of reference materials, JRC offering to the biotech companies to produce the reference materials (provided no other reference material producer does this), JRC is therefore enabling the implementation of EU GMO legislation;*
- *Support to EURLs outside JRC, e.g. EURL-AP (animal protein): Development of CRMs for the identification and quantification of animal by-products for the implementation of REGULATION (EC) No 1069/2009 and the REGULATION (EU) No 51/2013 and REGULATION (EU) No 56/2013 daughter legislations on the prevention, control and eradication of certain transmissible spongiform encephalopathies (Note: the method developed by the EURL requires a common CRM for calibration);*
- *Control of certain contaminants in food and feed specifically requires the use of CRMs, e.g. mycotoxins (REGULATION (EC) No 401/2006), dioxins and dioxin-like PCBs (COMMISSION REGULATION (EC) No 1883/2006), and lead, cadmium, mercury, inorganic tin, 3-monochloropropanediol and polycyclic aromatic hydrocarbons (REGULATION (EC) No 333/2007).*
- *EU legislation in the food/feed safety domain explicitly mentions the reference materials and the development and production may be linked to the designated EURL. Regulation (EC) No 882/2004 has designated forty five EU reference laboratories⁹ of which the JRC hosts the:*
 - *EU reference laboratory for additives for use in animal nutrition (EURL-FA);*

- *EU reference laboratory for genetically modified organisms (EURL-GMO);*
- *EU reference laboratory for materials intended to come into contact with foodstuffs (EURL-FCM);*
- *EU reference laboratory for heavy metals in feed and food (EURL-HM);*
- *EU reference laboratory for Mycotoxins (EURL-MYC);*
- *EU reference laboratory for Polycyclic Aromatic Hydrocarbons (EURL-PAH);*
- *EU reference laboratory for alternatives to animal testing (ECVAM).*

It includes among others rules on financing of official controls, administrative assistance and cooperation, enforcement and rules on controls on imported products.

Reference materials provided for EURLs contribute to a large extent to the implementation of EU legislation. This applies not just for EURLs for which the JRC is the designated laboratory; the JRC can also support other EURLs with reference materials where needed.

3.2.1.2 Reference materials for health diagnostics

We received the following examples of legislation that is implemented using reference materials for health diagnostics designed (and produced) by the JRC:

- *DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro medical devices (hereafter the IVD directive) is demanding traceability of values assigned to calibrators and/or control materials to common reference measurement procedures and/or reference materials of higher order (compliance with ISO 15194);*
- *JRC is producing higher order reference materials for in vitro diagnostics areas flagged to be of relevance for the society;*
- *These CRMs form in most cases - together with the corresponding reference method - the unique, globally used reference measurement system for the specific clinical biomarker.*

We gratefully use a description in the literature⁹ of the developments following the adoption of the European IVD directive in 1998 (first bullet above). When the directive was adopted, neither the above-mentioned “common reference measurement procedures” were available nor the “reference materials of higher order”. At the time the U.S. medical diagnostics industry supplied about 60 % of the EU market for such devices, but the absence of reference materials was more than just a problem for the U.S. Hence the BIPM and NIST took the initiative to set up a Joint Committee for Traceability in Laboratory Medicine (JCTLM) under the auspices of the BIPM, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC). The JCTLM subsequently set up two working groups, one on reference materials and reference procedures and the other on reference measurement laboratories. The IRMM along with other stakeholders supported the establishment of the JCTLM and provided useful input to the discussions.

The JCTLM has twenty eight member organisations, which include the major national laboratories, the diagnostic laboratories, diagnostic industry, standards bodies, regulatory bodies, reference material producers, health authorities, accreditation bodies, and quality assurance organisations. “IRMM” is one of the thirteen national and regional members¹⁰.

Created in 2002 in response to the implementation of the European Community’s IVD directive, the JCTLM pursues the more general goal of providing a worldwide platform to promote and give guidance on internationally recognized and accepted equivalence of measurements in Laboratory Medicine and traceability to appropriate measurement standards.

The reference materials of the IRMM at the time helped the JCTLM implementing small and very selective parts of the IVD directive with some good pioneering in new metrology in bioscience and pharmaceuticals. Some of the JRC’s contributions to JCTLM’s general work may be regarded as a contribution to the implementation of the IVD, keeping in mind that this complex and wide-ranging piece of EU legislation concerns over

500 000 devices on the market and 600-4000 clinical relevant biomarkers/ analytes/ parameters. Therefore JRC reference materials for health diagnostics are considered to make a modest contribution to the implementation of EU legislation.

3.2.1.3 Reference materials for environmental monitoring

We received the following examples of legislation implemented using environmental reference materials designed (and produced) by the JRC:

- *DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework for Community action in the field of water policy (“the Water Framework Directive”) plus amending DIRECTIVES 2008/105/EC AND 2013/39/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL stipulate the need to monitor priority hazardous substances in surface waters and biota to ensure a good water status in the EU;*
- *COMMISSION DIRECTIVE 2009/90/EC, laying down technical specifications for chemical analysis and monitoring of water status, demands that laboratories demonstrate their competence amongst others through the use of reference materials;*
- *The corresponding JRC reference materials have been tailored to the needs of these Directives (regarding matrix-analyte combination, concentration level of the analyte, uncertainty of the certified values);*
- *DIRECTIVE 2008/50/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on ambient air quality and cleaner air for Europe demands that the national laboratories are accredited according to EN/ISO 17025. JRC’s CRMs provide the necessary benchmark for quality assurance of those laboratories.*

The directives stipulate the need to use appropriate reference materials for chemical analysis and monitoring. The JRC takes care of the availability of several of these reference materials. In general it can be stated that the reference materials that the JRC provides in this field help implementing EU environmental legislation.

3.2.1.4 Engineering reference materials

We received the following examples of legislation that is implemented using engineering reference materials designed (and produced) by the JRC:

- *Support of Regulation (EU) 305/2011 and DIRECTIVES 1997/23/EC and 2009/105/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL by providing CRMs for testing of impact resistance of steel;*
- *Support of implementing DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the restriction of the use of certain hazardous substances in electrical and electronic equipment ('RoHS Directive') and the Waste Electric and Electronic Equipment Directive 2012/19/EU;*
- *Fuel & biofuel CRMs enabling the implementation of DIRECTIVE 2009/30/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fuel specifications and supporting DIRECTIVE 2009/28/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the promotion of renewable energy;*
- *Non-certified and certified reference materials for reliable and comparable measurements of the size of nanoparticles thus enabling the implementation of the COMMISSION RECOMMENDATION COM (2011)696 on the definition of the term 'nanomaterial'.*

We place on record that JRC engineering reference materials contribute to the implementation of EU legislation. However, this positive assessment needs to be considered together with the answers to questions about the European added value, intervention logic and prioritisation.

3.2.1.5 Nuclear reference materials

We received the following examples of legislation that is implemented using nuclear reference materials designed (and produced) by the JRC and that first of all the JRC sees its activities clearly identified in EURATOM Treaty.

- *With its safeguards activities the JRC helps the European Commission to fulfil its Treaty obligations, i.e. to exercise control of all civil fissile nuclear material in the EU. This task*

requires the availability of certain nuclear reference materials and can be seen as support to the implementation of the following EU legislation:

- *COMMISSION REGULATION (Euratom) No 302/2005 on the application of Euratom safeguards, and, related with this, Commission Recommendation (2006/40/Euratom) on guidelines for the application of Regulation (Euratom) No 302/2005;*
- *COMMISSION RECOMMENDATION (2009/120/Euratom) on the implementation of a nuclear material accountancy and control system by operators of nuclear installations.*

Moreover, by providing the nuclear quality control tools developed at the JRC, the European Commission can give assurance to governments and the citizen that the European nuclear industry, the European Union and its Member States comply with their legal duties under the Euratom Treaty and their international commitments to the Non-Proliferation Treaty.

3.2.2 IMPROVING GLOBAL COMPARABILITY OF MEASUREMENTS

To what extent do the JRC's reference-materials activities contribute to advancing measurement standards?

Many of the CRMs developed and produced by the JRC require new concepts for their characterisation and certification. In addition sometimes the JRC also introduces new technical approaches for material preparation. Examples are:

FOOD & FEED REFERENCE MATERIALS

- *GMO CRMs for difficult matrices (sugar beet, potato, rapeseed);*
- *A concept for certifying matrix GMO reference materials with respect to their DNA copy number ratio (first CRMs with certified values for both this ratio and the GM mass fraction released);*
- *Microbiological CRMs for identity determinations;*
- *Microbiological CRMs for precise counting of very low numbers of colony forming units.*

REFERENCE MATERIALS FOR HEALTH DIAGNOSTICS

- New concepts for characterisation and certification approaches are established in collaboration with external scientific institutions (reference labs).
- Development of CRMs goes hand in hand with the development of reference methods and stimulates each other (IFCC see Section 3.2.1.2);
- Some of the most innovative CRMs in this area are:
 - CRM for genetic testing of Factor II;
 - CRM with very low DNA copy number concentration for leukaemia monitoring;
 - CRM for autoimmune disease;
 - CRM for diabetes mellitus diagnosis and treatment control by HbA1c.
- JRC provides strong input to the development or revision of corresponding documentary standards in ISO, e.g. ISO 17511.

ENVIRONMENTAL REFERENCE MATERIALS

- New kinds of reference materials, which are closer to real environmental monitoring samples:
 - CRMs mimicking 'whole water' with humic acids and particulate matter;
- - CRMs from fish muscles in form of fresh-weight materials stored and shipped non-frozen;
- Support to standardisation (CEN), e.g. by reference materials supplied to CEN TC 230 for method validation.

ENGINEERING REFERENCE MATERIALS

- Development of concepts for the definition of measurands for nanoparticle sizing, and the characterisation and certification of related reference materials.

NUCLEAR REFERENCE MATERIALS

- *Most of the CRMs developed by the JRC respond to the needs and challenges of the IAEA in the field of Safeguards and Forensics.*

The JRC is member of the NetWork of Analytical Laboratories (NWAL) of IAEA as part of reference material producer.

- *These nuclear CRMs give access to the validation of innovative analytical methods on ultra-trace elements, based on mass spectrometry techniques.*

In summary JRC's reference materials contribute to a large extent to advancing measurement standards. This applies to some of the older, but in particular to the latest reference materials fully developed by the JRC laboratories in Geel.

3.2.3 CREATING EU ADDED VALUE¹¹

To what extent do the JRC's reference-materials activities contribute to creating EU-added value?

Reference material needs to satisfy very strict quality norms, irrespective of where and by whom it is produced. Whether the reference-materials provider serves private or national interests is irrelevant. Hence, in *sensu stricto*, a reference material developed or produced in-house by the European Commission has no additional value compared to a reference material created by a private or a member-state laboratory.

However, there can be EU-added value in reference-materials activities as such, for instance when the EU makes it possible to develop a material that is so complex or so costly that not one Member State would do this on its own. This was the rationale behind the BCR programme in the 1970s and still is the reason for EU support to metrology in its current appearance, the European Metrology Programme for Innovation and Research (EMPIR). The conclusion remains that there is no added value when the Commission produces this material.

In spite of these strict remarks about the EU added value of JRC reference materials, we like to stand up for the value of past and future development of reference materials by the JRC. The counterfactual situation, in which the JRC would not have done the job that it did, would have been quite negative compared to the current situation in which the JRC's active and often pioneering attitude led to valuable contributions in

the development of certain, in particular complex reference materials.

In the field of nuclear reference materials the EU added value is embedded in the institutional arrangement. Fulfilling a Euratom task for the Commission, the JRC provides nuclear CRMs as metrological tools for the European nuclear industry and safeguard laboratories to meet the requirements for accountancy measurements in compliance with the globally accepted International Target Values for Measurement Uncertainties in Safeguarding Nuclear Materials. Safeguards authorities, nuclear industry/ laboratories and research institutes worldwide use JRC's nuclear CRMs for accurate measurements of samples from all stages of the nuclear fuel cycle and for environmental sample analysis.

However the JRC is used to collaborating with other European and international producers in order to share production and commercialisation of these standards. A trend in this area is noted for collaborative development to share suitable purified raw material, costs and availability of suitable facilities. It is important to ensure that the price set will allow a return on all investments. Maintaining the balance between producers in the Member States and the JRC for the Commission ensures the continuity, reliability, quality and competitiveness of nuclear measurement in Europe.

3.2.4 CONTRIBUTION TO INTERNATIONAL CO-OPERATION

To what extent do the JRC's reference-materials activities contribute to international co-operation?

The JRC's reference-materials activities largely contribute to international co-operation. Some examples are:

- *The JRC is active in the ISO Committee on Reference Materials (REMCO), established with the aim of encouraging the harmonization and promotion of certified reference materials (CRMs). Here it supports the establishment of new and the revision of existing ISO Guides and other ISO deliverables in the area of reference-material standardisation;*

- *Most CRM projects are conducted with partners all over the world and stimulate scientific cooperation and benchmarking;*
- *JRC's experts from the reference-material projects are involved in activities of international committees and organisations, e.g. the JCTLM Committee (BIPM, IFCC, ILAC) defining Reference systems (CRMs, Reference methods, Reference labs) and publishing these in the JCTLM-database thus being available for industry to establish traceability to their kits;*
- *JRC input on reference-material topics to ISO and CEN technical committees in the areas of nanotechnology and particle sizing;*
- *Bilateral cooperation with the National Institute of Standards and Technology (NIST) on CRMs for nanotechnology;*
- *Safeguards agreements (INFCIRC) between the European Union, its Member States and the International Atomic Energy Agency (IAEA);*
- *Several formal agreements form the basis of JRC's international cooperation on nuclear CRMs; collaborative projects for reference-material development with DOE (U.S.), IAEA, CEA CETAMA are fundamental to keep the competence and standards available in Europe;*
- *At an international level, the JRC's nuclear certified reference materials serve the requirements of international agreements as the Treaty on the Non-Proliferation of Nuclear Weapons. JRC CRMs are used by the IAEA safeguards inspectors during their verifications of nuclear plants and nuclear activities worldwide.*

3.3 INFRASTRUCTURE AND FACILITIES

To what extent are the JRC's infrastructure and facilities appropriate for the reference-materials activities, also in a cost-effectiveness perspective?

The JRC's reference-material activities are carried out in state-of-the-art laboratory facilities including various analytical laboratories (trace element analysis, organic analysis, nucleic acid analysis, protein analysis, microbiological and

pathogen analysis and engineering material analysis) and some processing facilities for the manipulation and manufacturing of the wide range of liquid and solid materials that are unique amongst reference-material producers in Europe. A dedicated Reference Material Production Building hosts the majority of the reference-material processing activities, and recent refurbishments of the nucleic-acid-analysis and organic-analysis laboratories have ensured that JRC's laboratory facilities are state-of-the-art.

The JRC laboratories focus on special tasks. According to JRC scientists these are tasks for which no external expert contractor can be found (e.g. for specialised R&D tasks, new and/or unique processing procedures, certain high-accuracy measurements), which are time-critical (e.g. processing controls), or which have to be performed in-house because of contractual constraints (e.g. Intellectual Property Right (IPR) issues in GMO CRM projects).

The production of reference materials involves a range of different tasks (sampling of the starting materials, homogeneity measurements, stability measurements, characterisation of the materials etc.) all of which are not carried out by the JRC. However, the limitations for outsourcing have increased in recent years as, for instance, external pilot processing facilities were diminished in various industrial branches, or external laboratories tend to deliver routine measurement services at an insufficient performance level for reference-material projects. Therefore, the JRC is seeking an appropriate balance between in-house and outsourced tasks for each reference-material project, taking into account the necessary quality criteria for the final product.

The development of nuclear CRMs is exclusively carried out in the nuclear chemistry and nuclear mass-spectrometry laboratories. These nuclear-controlled area laboratories are providing, together with a clean laboratory area, the necessary infrastructure to carry out in a safe and secure manner actinide chemical separation, accurate weighing of actinides, mass-spectrometric analysis of actinide samples ranging from nuclear fuel material to the low environmental level, computerised automated

dispensing of actinide solutions, and production of actinide reference particles.

The JRC has a storage building dedicated to its reference materials. It has compartments and equipment to store materials at temperatures from -70°C to $+18^{\circ}\text{C}$ at controlled humidity. Some (C)RMs are even stored at -190°C in special containers. The building also hosts the distribution activities for non-nuclear reference materials, which are shipped via contracted courier services. The nuclear CRMs are separately stored in the nuclear zone of the JRC site in Geel and are distributed directly from the JRC to its customers.

Nuclear shipment is necessary during the production, certification and commercialisation phases; a time-consuming step needing specialised staff for the organization and planning and for the knowledge and following of national and international regulation and its evolutions. Furthermore it is not a specific task of reference-material production.

As a whole the JRC is equipped with state-of-the-art equipment for the development, production and storage of reference materials. This infrastructure facilitates the establishment of a top position amongst reference-material producers. Only a few institutes worldwide have the resources to equip their laboratories with a complete installation like in Geel.

The JRC's infrastructure and unique experienced individuals form a part of Europe's infrastructure, a European facility. If there is one critical remark to make here then it is that there should be a model to make these facilities available to others for use.

Regarding the cost-effectiveness it is not possible to make an assessment without a detailed analysis of cost, sales and price-setting. We appreciate that the managers of the activities have not prepared the detailed information that is required for a quantitative assessment. The claim during the presentations that the reference-material activities do not bring net profit is credible, the more so since the activities are subject to inspections by the EU Court of Auditors. Usually early research costs are not included in the price calculation, which may be considered a

noble act, but deviation from full-cost recovery bears the risk of distorting effects.

3.4 THE ERM TRADEMARK

To what extent does the ERM trademark facilitate the customers' choice for the appropriate reference material?

Besides SRM[®] of NIST, trademarks are a quite recent development in the field of certified reference materials (for example, Certipur[®], the trademark of CRMs from Merck KgA, and TraceCert[®], the trademark for CRMs from Sigma-Aldrich, were registered in 2005 and 2007, respectively). The BCR trademark also was only registered in 2001 to prevent other companies from using the BCR label established by the CRM programme of the European Commission.

The ERM[®] trademark was registered in 2007 (filed in 2003) specifically for CRMs of the ERM consortium. The JRC is part of this consortium as reference materials producer and signatory of the CIPM-Mutual Recognition Arrangement.

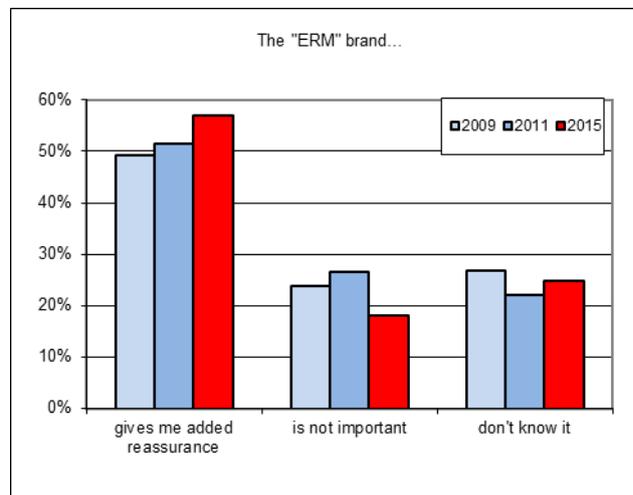


Figure 1. JRC Survey results showing customer confidence because of the ERM trade mark.

The JRC investigated the impact of the ERM brand in CRM customer satisfaction surveys in 2009, 2011 and 2015. As indicated in Figure 1 with survey results, a fraction of about 20 % of customers is not aware of the brand, however the results also show a steady increase of the customer portion who state that the ERM brand gives them added confidence.

In our view the availability of ERMs plays a positive role for a certain part of reference-materials market. Their availability serves the customer, which means there are benefits in having this trademark.

4 INTERVENTION LOGIC AND PRIORITY SETTING

4.1 THE INTERVENTION LOGIC

To what extent is there a (formal) intervention logic for the JRC's various activities in the field of reference materials?

Since the JRC's contributions to this field of reference materials have real impact, there are no incentives to question the JRC's formal *intervention logic* for its activities in this field. However, this evaluative question forces to think rigorously about JRC's role and responsibilities in this field. It forces to investigate whether the JRC thinks ahead in a logical way and how it establishes a causal chain that leads from a generic formulation in the JRC's programme to actual development and production of a specific reference material.

In their formal response to the panel, the JRC answered this question by providing a long list of directives and regulations, arguing that they all either directly or indirectly, require reference material for their implementation. This is presented as the justification for the selection of reference materials for development and productions. Since the Commission has proposed each directive, it should take care that the necessary reference materials are available for their implementation; and that the Commission's Joint Research Centre should do this.

This argument is indeed a convenient justification for action; convenient for those who benefit from the resources invested by the JRC in the often costly development and production of more complex reference materials; and sufficient justification for the use of resources and the work undertaken.

However, the argument that the organisation that proposes the use of reference material is also responsible for its availability is at odds with basic principles for regulators¹². The first principle for good governance is that of "role clarity". In fact, when the body that mandates the use of

reference material in its regulation also produces and markets this material, a conflict of interest situation is looming.

Indeed EU legislation does not stipulate the Commission's responsibility for the availability of reference material, for instance:

- EU regulations for the authorisation of GMO on the market only specify that the applicant for authorisation should include "information as to the place where the reference material can be accessed". Neither the Commission nor the EU Reference Laboratory (EURL) for GMO and Food and Feed need to produce this reference material. Legislation does not place the burden of developing and producing the reference material on anyone.
- The environmental legislation of the EU does not assign responsibility for the availability of reference materials.
- Arrangements to support the implementation of the IVD directive were made at international level in the JCTML around the turn of the century (see Section 3.2.1.2). The Directive itself does not assign this task to the JRC, but the JRC's intervention may have been in the spirit of its work programme at the time. About 15 years later, the involvement of the JRC in the JCTML is largely infrastructure driven.
- When the JRC produces CRMs for testing the impact resistance of steel it does this mainly because a framework-programme in 1996 entrusted the legacy of the BCR programme to the JRC. This applied for the duration of that framework programme and occurred in a time that there were strong ideas to evolve the JRC into an arm's length agency of the European Commission. Today, it is less obvious that a firmly integrated science and knowledge service of the European Commission is producing and marketing mechanical devices needed for tests required by EU legislation.

Moreover, the “bottom-up” nature of the rationale for support is today more striking. The development of reference materials to implement regulations for food and feed safety is expensive and none of the regulations explicitly require the JRC to develop or to produce them. The argument that “since nobody else does it, we have to do it” has been articulated in this context, but it lacks formal rigour.

In the background briefings and discussions, the JRC staff responsible for the reference-material activities argued fluently in support of their position as part of both the European Commission as well as being part of the international measurement infrastructure (metrology, standardisation, and accreditation). However, the evaluative question about the intervention logic forced us to look beyond the usefulness of the JRC’s contribution to the field. This led to the question whether the European Commission should at all host a function for the development and production of reference materials and whether it would be better to transfer production, marketing and after-sales services to an arm’s-length body.

As stated before, the global metrological community highly appreciates the JRC as a participant in the areas in which it is active. Since this metrological community on a global scale is not able to meet all demands for reference materials, they are faced with the need to pool and coordinate resources. In view of such scarcity, the questions of whether the JRC follows a formal intervention logic or whether its work aligns with the Commission’s priorities is not of direct concern for this community. The JRC’s contributions to this field have real impact; there is no question about their role and competence.

Nevertheless, the evaluative question addressed here has led to the conclusion that the JRC’s intervention logic for the development and production of specific reference materials outside the nuclear domain has largely been developed “bottom-up”. The way in which the JRC has filled certain gaps is highly commendable, but for an operational activity like this, transfer to an arm’s length body could be more sustainable in the overall institutional landscape.

Considering that this is not a short term-solution the JRC should practice the greatest transparency, and, in accordance with good practice guidelines, establish mandatory mechanism to make arising conflicts of interest transparent and resolve them.

4.2 PRIORITY SETTING

To what extent is the JRC’s priority setting for its activities in this domain rational and transparent?

Our assessment of the priority-setting mechanism for JRC’s nuclear-reference-materials activities is positive. The IAEA plays a central role and organises for instance technical meetings every three to four years to set priorities for the production and development of reference materials for nuclear safeguards. The JRC participates and follows this global coordination effort.

Outside the nuclear domain the situation is different and we refer to the ex-post FP6 evaluation report of the JRC¹³. This report was prepared in 2008 and already included some observations that are still pertinent to this question of priority setting for non-nuclear reference materials.

“An important aspect of this field is that there is no firm rule on which to decide the reference material that is the most relevant to be produced. Therefore, it is not surprising that in practice this decision depends on the in-house measurement and production capabilities and the available cooperative partners... to conclude with a good piece of advice, that ... reference materials and measurements work merits a special position in a long-term vision and an overall strategy for the JRC”.

Eight years later our review suggests that the situation in this field has not changed. Although it is not within the mandate of this evaluation to analyse work across the JRC that may be related to metrology, we made a quick search in the public database of European research programmes for metrology¹⁴ to link the situation in reference materials to the one in the broader field of metrology.

Table 1 shows the result of this search with a range of joint metrology projects between the JRC and NMIs, addressing subjects like biofuels, car emission measurement, photovoltaic classification, Volatile Organic Compounds (VOCs) indicators for the environment, highly-specialised reference materials, or the characterisation of nanomaterials. Each of these projects focusses on research but also has work packages addressing the dissemination of results and hence the future provision of new services. Like JRC's reference materials projects: they are well coordinated, bottom-up driven, but not strongly anchored as a typical task for the European Commission.

We have to take the view that each of the projects listed in Table 1 was correctly identified as a priority for funding. But they do raise a broader

issue, whether there should have been more coordination and whether the JRC activity is an indispensable part or merely a duplication of efforts carried out elsewhere? We return to these questions in Chapter 5.

European metrology is coordinated through the association of national metrology institutes EURAMET with an EU supported research programme. However, there is no central approach to decide which reference material is the most relevant to develop or to produce. Fortunately the JRC exercises enough coordination as well as collegial consultation to avoid unnecessary duplication, but the question remains how are the priorities set between all CRMs that the JRC could develop?

TABLE 1. JOINT PROJECTS BETWEEN JRC AND NMI'S IN THE EUROPEAN METROLOGY RESEARCH PROGRAMMES (EMRP, EMPIR)

| | Project No | Title |
|-----------|-------------|---|
| 1 | ENG08 | Metrology for New Generation Nuclear Power Plants |
| 2 | ENG09 | Metrology for Biofuels |
| 3 | ENG55 | Towards an energy-based parameter for photovoltaic classification |
| 4 | ENV01 | Metrology for Chemical Pollutants in Air |
| 5 | ENV02 | Emerging requirements for measuring pollutants from automotive exhaust emissions |
| 6 | ENV04 | European metrology for earth observation and climate |
| 7 | ENV05 | Metrology for ocean salinity and acidity |
| 8 | ENV08 | Traceable measurements for monitoring critical pollutants under the European Water Framework Directive (WFD-2000/60/EC) |
| 9 | ENV09 | Metrology for Radioactive Waste Management |
| 10 | ENV53 | Metrology for earth observation and climate |
| 11 | ENV54 | Metrology for decommissioning nuclear facilities |
| 12 | ENV56 | Metrology for VOC indicators in air pollution and climate change |
| 13 | ENV57 | Metrology for radiological early warning networks in Europe |
| 14 | HLT08 | Metrology for monitoring infectious diseases, antimicrobial resistance, and harmful micro-organisms |
| 15 | HLT10 | Metrology for biomolecular origin of disease |
| 16 | IND04 | Ionising radiation metrology for the metallurgical industry |
| 17 | IND57 | Metrology for processing materials with high natural radioactivity |
| 18 | NEW03 | Chemical and optical characterisation of nanomaterials in biological systems |
| 19 | EMPIR-SIP07 | Standard for Digital Data Format for Nuclear Instrumentation |

JRC scientists consider consultations with and requests from policy departments of the European Commission enough justification to undertake a reference material project. The same applies to written requests from the World Health Organisation (WHO) or the International Federation for Clinical Chemistry and Laboratory Medicine (IFCC). Nevertheless, we agreed unanimously that this prevailing “bottom-up” approach should be strengthened to bring greater scrutiny.

Whilst the JRC has a governing board with representatives of all EU Member States and Associated Countries, we identify the need for the

representation of external stakeholders and institutions in a dedicated review of the detailed strategy and plans for reference-material work. EURAMET can provide coordination with the established metrology infrastructure and it could provide an efficient forum to establish structured, consultations for the JRC. A formal selection board for JRC’s reference-material projects could come out of this.

Establishing an external review process for every project and reference-materials campaign would be useful too. As a secondary effect such review process would also produce new validation methods.

5 FUNDAMENTAL ISSUES FOR THE FUTURE

What are the fundamental issues for the (future role) of the JRC in the field of reference materials, (e.g. as developer, producer etc.) in relation to relevant European and international organisations?

5.1 GENERAL ISSUES

The assessment presented in Chapters 3 and 4 show that the JRC is a specialised player with competence and expertise built on:

- Well-equipped laboratories suitable for the production and analysis of high-quality reference materials;
- Experienced and highly-qualified staff;
- A stable mandate in nuclear measurements and standards, anchored in the Euratom Treaty with global coordination of priorities amongst three major players;
- A less stable mandate outside the nuclear domain in areas such as environment, food and feed safety, health aimed at highly-specialised interventions.

The JRC's contribution to the global reference material stock is respected and appreciated. However, it is no longer clearly anchored as a significant task or duty of the European Commission. Specifically, in our analysis we have noted that:

- The intervention logic for the reference-material activities is unclear (as summarised in Section 4.1);
- There is a risk of a conflict of interest arising between the regulatory function of the Commission and one of the Commissions own bodies (the JRC) also providing tools for implementation – and sometimes on a near-commercial basis (Section 4.1);
- The priority setting in the JRC's reference-material programme is largely “bottom-up” and consequently lacks transparency (Section 4.1);

- The activities of the Joint Research Centre are not formally engaged in the regional and global structures that provide metrology and measurement standards (Section 4.2).

The following paragraphs consider how these issues could be addressed, and highlight the special nature of the actions relevant to the nuclear reference materials.

5.2 ISSUES SPECIFIC TO NUCLEAR REFERENCE MATERIAL

The infrastructure for the provision of standards to underpin nuclear safeguards operates apart from the world metrology system, which is under the auspices of the International Bureau of Weights and Measures (in French, Bureau International des Poids et Mesures or BIPM) and the International Organization of Legal Metrology (in French, Organisation Internationale de Métrologie Légale or OIML). Here the JRC's position vis à vis the world metrology system has to be considered distinctly.

The European Commission operates an effective regional nuclear safeguard system (EURATOM) in close partnership with the International Atomic Energy Agency (IAEA) and in this context the Euratom Treaty mandates the JRC to set up a Central Bureau for Nuclear Measurements.

Specifically regarding reference materials for nuclear safeguards, there are three main producers of nuclear reference materials worldwide and global coordination is effected between them. Measurement norms and standards for nuclear energy applications are dealt with under nuclear authorities such as the IAEA. The JRC has a clear and stable mandate and fulfils this in close cooperation with the other relevant global players. This is a fundamental point of our assessment of JRC's reference-material activities. It underpins a clear role and duty for the JRC in the field of nuclear reference materials for the foreseeable future.

In this relatively stable field for nuclear reference materials the most likely scenario is one of stability and the JRC should be prepared for this.

One fundamental issue here is the huge European but also international challenge of decommissioning and dismantling (D&D) operations of nuclear sites and structures in the years, and indeed decades to come. The specific and complex reference materials for D&D operations are different from JRC's current CRMs and the JRC may want to investigate the consequences of this development for its activities in detail.

However, we cannot express more than the generalist's view that these developments should be picked up in the global coordination between the three main nuclear reference-material producers and that the JRC will find its position in this domain quite naturally. Considering its tasks under the Euratom Treaty and its experience and feedback in metrology (e.g. standards for reference-material production and certification) the JRC is expected to continue its contributions to the development and production of nuclear reference materials. This applies also to its participation in European projects via EMPIR and/or H2020 EURATOM calls for proposal (e.g. see Table 1 project number ENV 54).

Pricing policy in this domain remains an issue and the JRC should monitor the market to avoid disturbing other players, who have to work for full-cost recovery.

5.3 ISSUES FOR REFERENCE MATERIAL OUTSIDE THE NUCLEAR DOMAIN

5.3.1 PRIORITY SETTING

Irrespective of the longer-term development of the JRC's reference-material activities, priority setting in the possible interventions in this domain is a key issue. The way in which the JRC selects the reference materials that it develops and produces, outside the nuclear domain, has been a recurring point of criticism during the assessment.

Priorities now and in the past are set in a bottom-up approach in the closed circle of the JRC and the European Commission.

A transparent selection process and the authority of a representative selection board are fundamental for the effectiveness and the credibility of the priorities in the reference-material programme. There is of course also the need for a coherent intervention logic, but a well-organised priority setting based on external consultation will start to substantiate the relevance of the activities ahead of the renewal of the intervention logic.

Therefore, an external review process engaging with the stakeholder community which can prioritise reference-material activities is an immediate priority. A selection board could help improving the added value of the JRC's interventions in this field. Because of the global shortage of capacity in certain areas, there is even scope to look for accommodating prioritisation on a global scale. The European Commission (or whichever body they might designate) should convene a periodic meeting including NMI CRM producers to conduct a needs assessment and obtain commitments to fulfil requirements.

5.3.2 A VISION FOR REFERENCE MATERIALS ACTIVITIES

The trend analysis in Chapter 2 showed a strategic focus on reference materials during the FP4, FP5 and FP6 (1994-2006). The reference-materials activities expanded following Council's approval that the JRC could work against payment and its wish that it create additional income on the market. The transfer of the responsibility for BCR reference materials gave the JRC an additional boost.

However, the upward trend levelled off in FP7. That both the JRC's work programme under H2020 and the JRC's new strategy show considerably less ambition in this field could even be the sign of a downward trend for the provision of reference materials at the JRC. In any case reference materials are not in the centre of the JRC's current focus on knowledge creation and management. They are only loosely included in the long-term strategy.

For as long as JRC's activities in this field are based on a yearly adaptable mandate, it cannot be excluded that the JRC finds itself in a position where it has to give priority to direct policy support, which may put severe pressure on resources for reference-material activities. During this assessment the JRC showed no evidence of plans for an organised reduction of its reference-materials activities.

Noting this, we considered two scenarios. In our preferred scenario (1) the JRC continues with a rationalised contribution to reference materials within a new governance framework implemented "in house". In the alternative scenario (2) the JRC reduces its contributions in the field by transferring the relevant activities to an existing or to be created arm's length body.

- (1) The JRC continues a rationalised contribution to reference materials

Based on the availability of the well-equipped JRC laboratories in Geel (Belgium) this is a realistic short to medium-term scenario. The rationalisation envisaged is not the euphemism for reduction but rather the synonym for being more streamlined and effective within a new governance framework (see Sect. Governance within the context of the European metrology infrastructure 5.3.3 below).

The highest effectiveness can be achieved with a formal long-term commitment, with assigned responsibility for the BCR legacy, with a built-in duty to delegate and outsource tasks that can be carried out elsewhere, with a formal intervention logic for all of JRC's reference-material activities which includes a transparent selection process.

An upgraded governance framework should create "role clarity" to avoid conflict of interest between the regulatory function and the commercial provision of tools for the implementation of the regulations and directives.

If rationalisation unexpectedly would mean that the JRC can make fewer resources available for this work, then more effectiveness could also be achieved through a reorganisation of operational

tasks. There are models available, like for instance outsourcing everything except certification task which could represent a certain European added value.

- (2) The JRC gradually transfers its reference-material activities

The JRC has played a forerunner's role in reference-materials, pioneering in emerging areas and supporting new and complicated demands for applications in food safety, clinical chemistry and the environment. It has been a stimulating player in this field, but it could decide to reconsider its role. Being part of the regulating function in the EU requires careful governance for these activities (see Sect. 4.2), which can also be turned into a strong argument in favour of a gradual transfer of these activities to an arm's length body. This could be a European institute, an agency or any other existing or yet to be created quango¹⁵.

This alternative scenario is relevant in the longer term and would have significant consequences for the European and indeed the global reference-materials community. From a global perspective they would be mainly positive, but whether this scenario would ever be justified will depend on a large number of factors. For instance, it would be necessary for all stakeholders to agree on a centralised approach to reference material in Europe, well beyond "more coordination".

We cannot estimate the likelihood of this alternative scenario occurring, but an institutionalised, stronger coordination for metrology in Europe seems to us a *conditio sine qua non*. The second scenario offers the JRC an interesting vision to pursue, using its position inside the Commission to mobilise all partners and stakeholders as peers to discuss ways and means to make it happen. It offers a long-term perspective for the JRC not just for its reference materials, but for all its metrology-related activities. It would require the introduction of a higher level organisation for metrology in EU and reinforce Europe's position in metrology internally and globally, because it needs the support of all stakeholders.

5.3.3 GOVERNANCE WITHIN THE CONTEXT OF THE EUROPEAN METROLOGY INFRASTRUCTURE

As exemplified in Section 4.2, the JRC contributes to the European and global metrology infrastructure with more than just reference materials, but it has no formal membership relation with the metrology community. It is an uncommon situation, which may not be sustainable in the long run. Whether the JRC should continue to be a loosely bound organisation within the metrology community is another fundamental question. This fundamental question could be appropriately addressed in a structured discussion with the metrology community, involving the various stakeholders and the relevant departments of the European Commission.

Institutional discussions with the metrology community have to deal with traditional national systems for measurement science and measurement standards. They are the domain of the NMIs, who fully exercise their subsidiarity. Traditionally NMIs had little incentive to raise responsibilities above the national level. However, since a few decades the complexity and scale of requirements for quality-assured measurements in industry, and those associated with grand societal challenges are such that they cannot sufficiently be covered by the traditional, fragmented system. For this reason NMIs work together at the European level through membership of EURAMET, which coordinates the cooperation among NMIs in Europe and acts to create an integrated European Metrology Research system with critical mass and active engagement at regional, national, European and international level. This should lead to a fit-for-purpose and

truly coordinated metrology infrastructure in Europe with joint infrastructure and coordinated services where appropriate.

The analysis of the situation in reference materials given here indicates that the absence of a single political point of contact and a single institutional interlocutor for metrology questions in Europe makes it difficult to build synergy between scattered interests. Drivers for metrology are also spread over different political sectors (e.g. internal market, trade, industry, consumers, sustainability, international relations) and they are not particularly strong or focussed in one specific policy. Additionally, the interests go well beyond research.

Continuing in Europe with a distributed network of metrology players would weaken the position of the total in a globalising world. Therefore, the structured discussion that we propose should certainly aim at a centralised organisation with the NMIs as key players to manage for instance the decentralised development and production of reference materials in Europe.

The JRC could help to trigger the necessary dialogue between the various stakeholders. At the same time we believe that long-term solutions for JRC activities in reference materials are easier to find when they are made part of an overall approach to the JRC's metrology activities placed in the wider European context.

6 RECOMMENDATIONS

The reference-material activity at the European Commission's Joint Research Centre is one of the leading such programmes in the world in terms of its quality and relevance. Since this is a field where the specific demands for reference materials exceed what the leading actors can develop and supply, the JRC's contribution to the reference-material landscape in Europe and worldwide is welcome; the community makes good use of its products.

The level of technical expertise amongst JRC staff and the extent of investment in complex equipment make it a unique capability in Europe, which is not available on this scale within any Member State.

Above all we are of the opinion that the JRC's capacity to develop the most complex and technically challenging reference materials for the implementation of EU legislation should be maintained.

We conclude by making the following recommendations notably for by far the largest part of the JRC's reference-materials activities, which are not covered by its mandate under the Euratom Treaty:

- The JRC should establish a formal intervention logic for all its reference-materials activities, taking care of the possible conflict of interest between the European Commission mandating the use of reference materials in its regulations whilst also producing and marketing them.
- Under all circumstances and as soon as possible, the JRC should establish a priority-setting body or mechanism for its reference-materials activity. The involvement of all stakeholders (inter alia, representatives from EU industry and Euramet) will give added legitimacy to the activities, and will support the development of the intervention logic.

- The JRC should establish an external review process at the project level engaging with the stakeholder community to help prioritising reference-materials activities. As a secondary effect, such a review process may also lead to new or improved methods.
- If further economic rationalisation of the reference-material activities is needed, the JRC could consider existing models for splitting the work such that development and production is outsourced so that the JRC can focus on the technically-demanding coordination and certification tasks.

The implementation of these recommendations will require the JRC to engage in a structured discussion with all stakeholders and in particular with the metrology community in order to position the reference material activities in the wider European metrology landscape.

Our recommendations are based on the presumption that they are implemented by the JRC "in-house". An alternative which we have not specifically considered would be for them to be addressed in the context of an organisation established at arm's length from the JRC.

This is a question that would need much further engagement with all stakeholders particularly the metrology community in Europe, which is currently engaged in running a substantial EU-funded research programme (EMPIR). As follow-on actions to this programme come to be considered, it would be timely to consider the role of reference-material activity at the JRC within them.

GLOSSARY

| | |
|----------------|--|
| BCR | Community Bureau of References |
| BIPM | International Bureau of Weights and Measures |
| CEA | French Alternative Energies and Atomic Energy Commission |
| CEN | European Committee for Standardisation |
| CETAMA | French Analytical Methods Committee |
| CRM | Certified Reference Material |
| D&D | Decommissioning and dismantling |
| DG | Directorate-General |
| DOE | US Department of Energy |
| EC | European Community |
| ECVAM | European Centre for the Validation of Alternative Methods |
| EMPIR | European Metrology Programme for Innovation and Research |
| ERM | European Reference Materials trademark |
| EU | European Union |
| EURAMET | European Association of National Metrology Institutes |
| EURL | European Union Reference Laboratory |
| FP | Framework Programme |
| FP6 | Sixth Framework Programme |
| FP7 | Seventh Framework Programme |
| GMO | Genetically Modified Organism |
| H2020 | Horizon 2020 |
| IAEA | International Atomic Energy Agency |
| IFCC | International Federation of Clinical Chemistry and Laboratory Medicine |
| ILAC | International Laboratory Accreditation Cooperation |
| INFCIRC | IAEA Safeguard documents |
| IRMM | Institute for Reference Materials and Measurement |
| ISO | International Organisation for Standardisation |

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| IVD | In vitro diagnostic medical devices |
| JCTLM | Joint Committee for Traceability in Laboratory Medicine under the auspices of the BIPM |
| JRC | Joint Research Centre |
| NGO | Non-Governmental Organisation |
| NIST | U.S. National Institute of Standards and Technology |
| NWAL | NetWork of Analytical Laboratories of the IAEA |
| OECD | Organisation for Economic Co-operation and Development |
| OECD-NEA | Nuclear Energy Agency of the OECD |
| OIML | International Organization of Legal Metrology |
| QUANGO | QUasi-Autonomous Non-Governmental Organisation |
| R&D | Research & Development |
| REMCO | ISO Committee on Reference Materials |
| SRM | Standard Reference Material |
| U.S. | United States of America |
| VOC | Volatile Organic Compounds |
| WHO | World Health Organisation |

ANNEX: TERMS OF REFERENCE FOR AN EVALUATION PANEL

Background

The European Commission's Joint Research Centre (JRC) has a well-established capability¹⁶ for the development and production of certified reference materials (CRMs). In 1960 it started a Central Bureau for Nuclear Measurements in Geel (Belgium) as part of the Commission's tasks under the Euratom Treaty.

In 1973 the Commission established a Bureau Communautaire de Références (BCR) with the mandate to organise interlaboratory studies and to certify materials using existing laboratories in the Member States. From 1987–2002 this BCR became part of the European Community research framework programmes. The JRC institute in Geel with its experience in producing nuclear standards and references was involved in the BCR programme off and on. In 1993 the JRC changed the name of the institute into the Institute for Reference Materials and Measurement (IRMM). Eventually, in 1995 the JRC took over full responsibility for the management of the BCR CRMs, including storage, distribution and stability monitoring. At the same time the JRC became involved in the development of new measurement standards to meet emerging needs in for instance food control and clinical chemistry.

Today, the JRC's certified-reference-materials catalogues contain more than 800 different materials available under the BCR, IRMM and ERM¹⁷ brands. More than 700 materials are related to environmental analysis, the analysis of food and feeding stuff, clinical chemistry, industrial applications and isotopic measurements, or certified for physical properties. A further more than 100 are nuclear certified reference materials.

The JRC is currently establishing a long-term strategy, which requires substantiation and a regular update of the rationale and vision for the various fields in which the JRC is active. For this purpose the JRC is convening a panel of external experts for the evaluation of its activities in the field of (certified) reference materials, also in line with the recommendation of the ex-post FP7 evaluation¹⁸ that the Joint Research Centre (JRC) should conduct dedicated sectoral evaluations.

Objectives and scope

The objectives of the evaluation are:

- To offer an account of the work and the achievements of the JRC in the field of (certified) reference materials
- To assess the relevance of the various parts of the JRC's reference materials programme in a European as well as in an international (global) context;
- To provide the JRC management with recommendations for future priorities regarding the JRC's reference-materials activities.

The evaluation should focus on: efficiency, effectiveness, relevance, coherence and EU added value (cf. endnote 11), i.e. the five evaluation criteria of the

Commission's Better Regulation Guidelines. It should help to obtain an independent view on the effectiveness and efficiency of all related activities and projects and look at their output and impacts in a cost-benefit perspective.

The scope of the evaluation encompasses all reference materials developed, produced and/or distributed by the JRC including those for nuclear analytical techniques. The historical perspective of reference-materials development and production is relevant for the evaluation, but in principle the evaluation should cover the activities over the last ten years (2006-2015). The evaluation should include a forward look to help the JRC long-term strategy addressing the science and technical support required by the EU.

The evaluation questions

- In which sub-areas of this field does the JRC have a unique role and/or is the use of its competence essential?
- To what extent are the JRC's infrastructure and facilities appropriate for the reference-materials activities, also in a cost-effectiveness perspective?
- To what extent do the JRC's reference-materials activities contribute to
 - the implementation of EU legislation?
 - advancing measurement standards?
 - creating EU added value?
 - international co-operation?
- To what extent does the ERM trademark facilitate the customers' choice for the appropriate reference material?
- To what extent is there a (formal) intervention logic for the JRC's various activities in the field of reference materials?
- To what extent is the JRC's priority setting for its activities in this domain rational and transparent?
- What are fundamental issues regarding the (future) (role) of the JRC in the field of reference materials, e.g. as developer, producer, in relations to relevant European and international organisations?

The evaluation panel

The evaluation panel will consist of five high-level external experts including the Chair. The JRC Director General will select the experts, nominate them through expert contracts and appoint one person to chair the group.

The character of the exercise requires that the experts cover a broad range of expertise (e.g. scientific, technical, economic and politico-institutional) and that the composition of the Panel respects equal gender opportunity.

Working method, deliverables and timetable

The Panel carries out the evaluation according to these Terms of Reference following the objectives and answering the evaluation questions.

The Panel will build its assessment largely on written information in background documents, an extensive self-assessment report, bibliometric analyses and market analyses, all provided by the JRC. To help its judgement the Panel may want to complement its impressions through JRC presentations, additional punctual expertise, or through contacts with beneficiaries of JRC activities.

The JRC's Adviser for Evaluation and Scientific Integrity assists the Panel in organising all aspects of the evaluation, makes available a secretariat to the Panel and assists in establishing the final report.

During the kick-off meeting the experts may propose to provide specific deliverables in the form of individual contributions to the final report.

The ultimate deliverable is the final evaluation report, counting a maximum of 30 pages - including an executive summary, excluding annexes - with an analysis of findings and a set of conclusions and recommendations based on evidence. The JRC will make the final report available to its stakeholders and the public.

Proposed timing:

- February 2016: Appointment experts
- March 2016: The JRC provides a Self-Assessment Report to the Panel.
- April 2016: The kick-off meeting @JRC in Geel; establish an outline of the final report that addresses the evaluation questions; possible request for further information.
- May 2016: Mid-term discussion; preliminary results are included in the first draft report. List of possible recommendations.
- June/July 2016: Final discussion of the findings and list of recommendations in the completed draft final report; report to be finalised in written procedure.
- July/August 2016: Final report ready

The Evaluation Panel may choose to schedule some of their discussions by audio or video conference.

11/04/16

discussed and accepted by the Panel

ENDNOTES

- ¹ “JRC Strategy 2030”, https://ec.europa.eu/jrc/sites/jrcsh/files/jrc-strategy-2030_en.pdf
- ² This terminology is specific for the European Community research programmes. From the beginning they distinguish direct research, which is carried out within the European Commission’s Joint Research Centre and indirect research, which is carried out at research centres, universities or enterprises, with partial financial assistance from the EU or Euratom. The BCR was an early indirect research action programme in 1973, more than a decade before the start of the first Framework Programme in 1984.
- ³ DECISION No 1110/94/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 April 1994 concerning the fourth framework programme of the European Community activities in the field of research and technological development and demonstration (1994 to 1998).
- ⁴ The diversification of the JRC is an evolution between 1970s and the 1990s during which the JRC’s work programme branched out into areas beyond the nuclear domain. The greatest change took place between 1988 and 1998 when the ratio of the JRC’s resources for nuclear/non-nuclear research inverted from 3:1 to 1:3.
- ⁵ Implementing acts are non-legislative acts adopted in order to implement the legally binding acts of the European Union on which they are based (here the legally binding acts are Horizon 2020 and the Euratom Research and Training Programme).
- ⁶ COMMISSION IMPLEMENTING DECISION of 11 February 2016 on the adoption of multi-annual work programmes under Council Decision 2013/743/EU establishing the specific programme implementing Horizon 2020 – The Framework Programme for Research and Innovation (2014-2020) and under Council Regulation (Euratom) No 1314/2013 on the Research and Training Programme of the European Atomic Energy Community (2014-2018) complementing the Horizon 2020 Framework Programme for Research and Innovation, to be carried out by means of direct actions by the Joint Research Centre for the period 2016-2017, and amending Commission Implementing Decision C(2015) 784 on the adoption of multi-annual work programmes for the period 2015-2016 C(2016)730.
- ⁷ JOURNAL OF LAW AND SOCIETY, VOLUME 39, NUMBER 1, MARCH 2012, ISSN: 0263-323X, pp. 20±38, The Pragmatic Sanction of Materials: Notes for an Ethnography of Legal Substances, by Javier Lezaun
- ⁸ There were 26 EURLs in 2004. From then until 2012 the number of EURLs for feed and food increased from 13 to 27 and the EURLs for animal health and live animals from 13 to 18.
- ⁹ “From Artefacts to Atoms: the BIPM and the search for ultimate measurement standards” by Terry Quinn, Oxford Press 2012, ISBN 978-0-19-530786-3, page 325
- ¹⁰ <http://www.bipm.org/en/committees/jc/jctlm/members-jctlm.html>
- ¹¹ European added value is a key criterion for spending at EU level. In general terms, it is the additional value resulting from an EU intervention compared to the value that would have been otherwise created by member-state action alone, Commission Staff Working Paper “The added value of the EU budget”, SEC(2011) 867 final.

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- ¹² OECD(2014), "Role clarity", in The Governance of Regulators, OECD Publishing, Paris. DOI: <http://dx.doi.org/10.1787/9789264209015-6-en>
- ¹³ Ex-post FP6 (2002-2006) evaluation of the direct actions of the Joint Research Centre, https://ec.europa.eu/jrc/sites/jrcsh/files/jrc_eval_report_2008_09_expost_fp6.pdf
- ¹⁴ The first programme was EMPR subsequently supported by the European Commission through ERA-NET Plus, Article 169 of the TFEU and for the last part (2009-2014) through Article 185 of the TFEU. The current programme EMPIR (2015-2020) is also based on article 185 of the TFEU.
- ¹⁵ A quango or a quasi-autonomous non-governmental organisation is an arm's length bodies created and funded by the government, outside its civil service. Quangos enjoy operation independence, generally perform regulatory or watchdog functions, or engage in commercial and semi-commercial activities which a government usually may not.
- ¹⁶ Accredited to ISO Guide 34 for the production of certified reference materials (accreditation by the Belgian Accreditation body BELAC - Registration No. 268-RM)
- ¹⁷ ERM is the registered trademark for European Reference Materials
- ¹⁸ EUR 27343 - Ex-post evaluation of the direct actions of the Joint Research Centre under the Seventh Framework Programmes 2007-2013 (2015), ISBN 978-92-79-49548-9,doi: 10.2760/94480

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