

EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods

Competitiveness in the Pharmaceuticals Industry and Biotechnology

Brussels, 10th October 2008 M/429

MANDATE ADDRESSED TO CEN, CENELEC AND ETSI FOR THE ELABORATION OF A STANDARDISATION PROGRAMME FOR BIO-BASED PRODUCTS

1. SCOPE

This mandate concerns the development of a programme for European Standards and/or other standardisation deliverables for BIO-BASED PRODUCTS taking note of all aspects linked to the different specific products covered (see mandate addressed to CEN for the development of European Standards and CEN Workshop Agreements for bio-polymers and bio-lubricants in relation to bio-based product aspects – Mandate N° M/430). It also relates to the review of already existing European standard and other standardisation deliverables including possible revision and taking specifically and effectively into account the specific standardisation-related aspects, conclusions and proposed activities for bio-based products lead markets as outlined in the REPORT OF THE TASKFORCE ON BIO-BASED PRODUCTS composed in preparation of the Communication "A Lead Market Initiative for Europe" {COM(2007) 860 final} entitled "Accelerating the Development of the Market for Bio-based Products in Europe".

2. **JUSTIFICATION**

2.1 Political Context

The Competitiveness Council¹ invited the Commission "to present during 2007 an initiative on lead markets, based on a broad stakeholder consultation for defining a valid approach for fostering emergence of markets with high economic and societal value. This would include identifying areas where concerted action through key policy instruments and framework conditions, coherent and coordinated policy making by relevant public authorities, as well as enhanced cooperation between key stakeholders can speed up market development, without interfering with competitive forces."

In response, a Communication on a lead market initiative (LMI)² was launched. This Communication identified a first set of markets with potential to become LM. It calls for

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¹ Conclusions of 4 December 2006 on innovation policy and competitiveness.

² COMMUNICATION FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - A lead market initiative for Europe, COM(2007) 860 final, Brussels, 21.12.2007

urgent and coordinated action through ambitious action plans for these markets, to rapidly bring visible advantage for Europe's economy and consumers. The LMI approach was endorsed by the Competitiveness Council of May³. It aims at balancing the efforts to complete the supply side of innovation (e.g. R&D funding) with a demand-driven approach. The launch of a Lead Market Initiative (LMI) for Europe is one of its notable strategic priorities.

2.2 Rationale

September 2006

According to a recent study the 2006 volume of markets for **bio-based products** might more than triple until 2020 to an estimated 250 billion Euro globally, which could result in a similar increase in jobs (380,000). As of 2005, bio-based products already accounted for 7% of global sales and around 77 billion Euro in value within the chemical sector. The EU industry accounted for approximately 30% of this value.

Innovation policy in the European Union now⁴ applies a wide range of policy instruments to create a more favourable business climate for innovative goods and services. In the next few years, the implementation of the LMI will be at the heart of the deepening and implementation of the EC's innovation strategy. This calls for urgent and coordinated action through ambitious action plans for the identified areas, to rapidly bring visible advantage for Europe's economy and consumers.

One of the important features of the action plans (one for each lead market area) is to speed up the implementation of standardisation work. Since the action plans consist of a short time frame, it is important that during the first months of the LMI a strong drive towards implementation of the activities in the bio-based and other lead market areas is made.

The Lead Market Initiative (LMI) Communication concluded that standards may facilitate the development of Lead Markets. Standards should preferably be performance-based, yet technology-neutral. Regarding bio-based products⁵ standards are seen as essential

⁴ Communication "Putting knowledge into practice: A broad-based innovation strategy for Europe" of

3 2871st Competitiveness Council meeting Brussels, 29 and 30 May 2008

excluded even though these products are based on bio-mass, the reason being that for these products there are not the same kind of market failures that might be at hand for new bio-based products. However, wood based production is affected by the development of the bio-fuels demand and pulp and

⁵ Definition used: Bio-based products ("Bio" refers to "Renewable biological resources" and not "biotechnology". While advances in life sciences and biotechnology are a major driver for optimising biomass production and for bio-product innovations, there are other technology drivers, such as chemistry, nanotechnologies, etc.) refer to non-food products derived from biomass (plants, algae, crops, trees, marine organisms and biological waste from households, animals and food production). Bio-based products may range from high-value added fine chemicals such as pharmaceuticals, cosmetics, food additives, etc., to high volume materials such as general bio-polymers or chemical feed stocks. The concept excludes traditional bio-based products, such as pulp and paper, and wood products, and biomass as an energy source. As far as bio-fuels are concerned, it is essential to consider the link between the production of bio-fuels and bio-based products. This could occur in so called "bio-refineries". The technologies to produce bio-fuels and bio-based products, or their intermediate chemical building blocks, follow the same principles. Bio-based products have the potential of reinforcing the economics and rapid introduction of bio-fuels and vice versa. Moreover, conventional paper and wood products are

elements in aggregating initial demand, in particular for new bio-based products. In the area of bio-based products, an industry self-commitment concerning biodegradable and compostable polymer products exists since 2004, while another one for "Bio Hydraulic Oils" as part of bio-lubricants is current being prepared. This was facilitated by the Commission through a working group on renewable raw materials (RRMs) for industry and consists of a voluntary certification and labelling scheme. These commitments are seen as the starting point towards a harmonised internal market for bio-based products. It is essential to further build upon the biodegradability standards, e.g. stronger standards for lubricants in forest and agricultural machines to boost the use of bio-lubricants for this application. It was concluded that a coherent concept for bio-based product standardisation is needed, taking into account existing Commission policy on standardisation, as outlined in the Commission Communication on the role of European standardisation in the framework of European policies and legislation (COM(2004) 674 final) and the Communication 'Towards a greater contribution from standardisation to innovation in Europe (COM(2008) 133 final).

Consequently and on the basis of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, the Commission is launching this mandate to explore the potential of EU wide bio-based product standards.

Furthermore, the need for environmental and other sustainability criteria for such European standards and other standardisation deliverables should be considered by taking into account that final end products might be made up of a mix of bio-based and non bio-based components. In view of the importance of taking a life cycle perspective for evaluating bio-based products and fulfilling the mandate of the IPP Communication⁷, the EC services of the Joint Research Centre and DG Environment are currently developing a guidance handbook for good practice in Life Cycle Assessment, as basis for more robust practice analysis: the International Reference Life Cycle Data System (ILCD) Handbook. This handbook acts within the ISO 14040 series, but provides clearer guidance, avoiding subjective choices and ambiguities. The handbook has also been developed in coordination and consultation with EU industry and international partners including UNEP, Japan, China, etc.. This handbook is scheduled to be published in 2008. In the EU it also supports the implementation of the EC's Thematic Strategies on the Sustainable Use of Natural Resources and on Waste as well as the upcoming SCP Action plan.

paper production plants have in principle the technical potential of becoming bio-refineries. The current forest-based industries can therefore be affected by the developments in lead markets for bio-based products.

⁶ The notification costs of this voluntary scheme are ~7000€ per product linked to the execution of standardised tests (i.e. EN13432), while the additional certification costs are ~1400€ per product for the first year and ~1200€ per product for each of the following years. Companies include: BASF AG (DE), Cargill Dow (USA), Novamont (IT), Rodenburg Biopolymers (NL). It is supported by EU federations: IBAW, Plastics Europe, and ERRMA. More information on www.errma.org. Some bio-lubricants would also qualify for an ECO-Label (see Commission Decision N°2005/360/EC of the 26 April 2005 establishing the ecological criteria for the award of the Community eco-label to lubricants – OJ L 118/26, 5.5.2005).

⁷ COM(2003) 302 final

3. DESCRIPTION OF THE MANDATE

In order to promote the bio-based product lead market, CEN, CENELEC and ETSI are invited to execute the following tasks, taking full account of and building upon – as appropriate – the REPORT OF THE TASKFORCE ON BIO-BASED PRODUCTS composed in preparation of the Communication "A Lead Market Initiative for Europe" {COM(2007) 860 final} entitled "Accelerating the Development of the Market for Biobased Products in Europe":

- Explore the potential of European standards and other standardisation deliverables for bio-based products and review the already existing standards including also considering their possible revision as well as examining at the same time the potential for a single bio-based product standard;
- Develop a programme (including a suitable and realistic roadmap) of European standards or other standardisation deliverables for bio-based products, taking into account specific technical performance and descriptive standards for EU wide bio-based products as well as related measurement, testing, biodegradability, compostability, product functionality, impact on greenhouse gas emissions, the amount of different renewable raw materials (RRMs) and/or different bio-based content used during the manufacturing of various bio-based products and harmonised LCA procedures needed to prove specially required technical performance criteria;
- Consider reference to the International Reference Life Cycle Data System (ILCD) Handbook to ensure consistency with European and international recommendations for essential consistency and quality assurance, while avoiding repetition and the development of potentially conflicting new recommendations;
- Identify the availability of special stakeholders in relation to bio-based products in the EEA with a view to associate them when necessary in the standardisation process.
- Identify and prioritise possible needs for pre-and co-normative research relevant to the development of European standards or other standardisation deliverables for bio-based products including justification and an indicative time schedule for such an activity.
- Take into account as far as possible the work being carried out under mandate M/XXX (mandate addressed to CEN for the development of European Standards and CEN Workshop Agreements for bio-polymers and bio-lubricants in relation to bio-based product aspects).

CEN, CENELEC and ETSI are requested to take into account on-going pre-and conormative research and development (including relevant work done by relevant stakeholders, industry, in national as well as international fora and the Commission's Framework Programmes for research i.e. FP6 and FP7; CIP; Life+; etc.) and co-ordinate their activities in order to avoid any duplication of work as well ensure the generation of a clear priority list for future activities (see especially the last bullet point above). In this respect, it is also essential that any other relevant research activities/projects from various sources (e.g. European, National and Regional and Industry (here, especially the ETPs – see also below) Programmes) are taken actively and effectively into account. Moreover, they should also establish and/or build upon existing appropriate links for the above described tasks with relevant European Technology Platforms (ETPs), especially with the ones entitled Sustainable Chemistry (SusChem) (linked to the integrated and diversified biorefinery and renewable/regrowable raw materials related activities), Plants for the Future (linked to renewable/regrowable raw materials and waste as raw material for non-food use), Forest Based Sector (linked to renewable/regrowable raw materials and waste as raw material) and Biofuels (noting that as far as bio-fuels are concerned to consider just the link between the production of bio-fuels and bio-based products – see also footnote 6 of this mandate) to ensure a coordinated and fast progress of their tasks.

Furthermore, identified needs for environmental and other sustainability criteria for European standards or other standardisation deliverables bio-based products should also be consistent with work carried out and priorities set by the REPORT OF THE TASKFORCE ON BIO-BASED PRODUCTS composed in preparation of the Communication "A Lead Market Initiative for Europe" {COM(2007) 860 final} entitled "Accelerating the Development of the Market for Bio-based Products in Europe".

European standardisation efforts should also be elaborated wherever possible in cooperation with the international standards bodies and take into account in particular the ongoing activities in other parts of the world (i.e. activities in the USA and Japan especially in relation to: (a) test methods for determining the bio-based content of natural range materials using radiocarbon and isotope ratio mass spectrometry analysis; (b) practice for evaluating and reporting environmental performance of bio-based products; (c) guidance for the determination of bio-based content, resources consumption, and environmental profile of materials and products; and (d) guidance for sampling and reporting of results for the determination of the bio-based content of materials via Carbon Isotope Analysis or other approaches) into account.

4. EXECUTION OF THE MANDATE

The Commission hereby asks CEN, CENELEC and ETSI to fulfil the tasks as described above, while taking into account the rationale of this mandate stated in the justification.

CEN, CENELEC and ETSI are required to keep close contacts with the Commission and to ensure that their activities are co-ordinated in a way to create a consistent and coherent framework at the international level, notably with regard to OECD activities.

The report will be provided within 18 months after the acceptance of the mandate.

5. BODIES TO BE ASSOCIATED

The execution of the mandate should be undertaken in cooperation with the widest possible range of interested groups: The Joint Research Centre of the European Commission, OECD Activities as well as research institutes, and the different relevant technology platforms (see section 4 of this mandate).

As appropriate, CEN, CENELEC and ETSI will invite the standardisation stakeholders representing consumers' interests (ANEC), environmental protection (ECOS), workers (ETUI-REHS), SMEs (NORMAPME), European Renewable Raw Materials Association

(ERRMA), European Bioplastics (European branch association representing industrial manufacturers, processors and users of bioplastics and biodegradable polymers (BDP) and their derivative products), European Association for Bioindustries (EuropaBio), Comité Européen des Transmissions Oléohydrauliques et Pneumatiques (CETOP) or the European Fluid Power Committee, relevant activities under the Europe Innova Initiative, relevant European Technology Platforms (ETPs) and others to take part in the development of the programme.