



# Brussels News Update

## August 2010

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### FP7 - Europe's Biggest Ever Package of Research and Innovation Investment

As reported in last month's Brussels News Update, the Commission has published its work programme and associated 'Call for Proposal' dates. The total budget for the recent calls is €6.4 billion. It is expected to create more than 165,000 jobs. Máire Geoghegan-Quinn said that this was proof that Research and Innovation are at the heart of the EU's political agenda. There is a strong emphasis on SME involvement, with some fields setting a minimum percentage to be allocated to SMEs. There are many elements of interest to

chemists, including, €210 million allocated to material for environmental friendly production, €145 million allocated to new materials for energy generation, storage and efficiency and €240 million for the 'bio- economy' which is focused on using renewable biological resources as inputs into different sectors, including the production of chemicals, detergent and fuels.

**Source:** <http://europa.eu1>

### Resource Efficiency Highlighted in Annual Environmental Policy Review

The Policy Review is a report on environmental trends and policy developments at an EU and national level. The report focuses on the four priorities of the Environmental Action Programme: - Climate change; Nature and biodiversity; Health and environment; and, Waste and natural resources. Commissioner for the Environment Janez Potočnik, highlighted resource efficiency as an area where further EU and national policy measures were needed.

**Source:** <http://europa.eu2>

### JRC Announces Strategy for the Next Ten Years

The Joint Research Centre, has outlined a new vision 'to be a trusted provider of science-based policy options to EU policy makers to address key challenges facing our society, underpinned by internationally-recognised research'. The JRC will provide scientific support to the Chief Scientific Adviser (CSA) to the European Commission, announced in September 2009 and not yet appointed. The JRC will take a more multi-disciplinary approach and become more involved in 'horizon scanning and foresight intelligence'. The JRC will have a stronger focus on the Commission's 2020 strategy priorities, (innovation Europe, resource efficient Europe...) and the 'Grand Challenges', (such as global warming, energy supply and security, poverty, water scarcity and quality, food supply and quality, ageing society, public health).

**Source:** <http://ec.europa.eu1>

### European Parliament asks JRC, what is a nanomaterial?

Responding to a request from the European Parliament, the JRC has published a report entitled "Considerations on a definition of nanomaterial for regulatory purposes". Despite the growing utilisation of engineered nanomaterials in consumer products and innovative technological applications, there is at present no widely accepted definition of the term "nanomaterial" that is suitable as a basis for legislation on their safe use. The report discusses possible elements of a definition aiming at reducing ambiguity and confusion for regulators, industry and the general public. It recommends that the specific term "particulate nanomaterial" should be employed in legislation to avoid inconsistencies with other definitions and that size should be used as the only defining property. Taking a size based approach (1nm – 100nm) is not a straightforward choice according to the JRC and they argue that further 'stakeholder' consultation with the 'world of academia, regulatory bodies, industries and possibly NGOs' will be needed.

**Source:** <http://ec.europa.eu2>

### Confidentiality of IUPAC names in the Classification and Labelling Inventory

The European Chemicals Agency (ECHA), which implements the REACH Directive has announced that companies not registering for the 2010 deadline, but who are obliged to notify ECHA on 3<sup>rd</sup> January 2011 can keep their IUPAC name confidential and excluded from the classification and labelling inventory in certain circumstances, these include when the chemicals are non-phase substances; substances used as intermediaries; in scientific research and development and in product and process oriented research and development.

**Source:** <http://echa.europa.eu>

### **ECHA Data Sharing Form**

ECHA's data sharing web pages have been updated to show how companies can contact ECHA when data on vertebrate animal studies are not shared in a SIEF (Substance Information Exchange Forum), before or after the submission of a joint registration dossier. There is a new web form available to notify this type of data sharing dispute to ECHA. To facilitate finding information relating to data sharing disputes, ECHA has transferred the information contained in its web pages to a Questions & Answers on Data sharing and related disputes. Potential registrants of the same substance must share at least data involving tests on vertebrate animals in order to meet their requirements for registration. It is the responsibility of the negotiating parties to make every effort to reach an agreement on the costs of sharing that information in a fair, transparent and non discriminatory way. ECHA can assist companies that, in spite of their efforts, have failed to reach an agreement on data sharing. However, the parties involved should exhaust all options for negotiations before seeking ECHA assistance.

**Source:** [http://echa.europa.eu/news/press\\_en.asp](http://echa.europa.eu/news/press_en.asp)

### **Chemicals Agency Updates Safety Assessment Software**

ECHA's Chemical safety assessment and reporting tool, Chesar, has been updated to allow companies to create a full Chemical Safety Report. Chesar provides industry with a way to carry out the Chemical Safety Assessment more efficiently and effectively. In particular, the tool supports the exchange of assessments or parts of it among registrants and industry associations. Also, it supports cross-industry standardisation on how to describe and communicate the conditions of safe use. This information is then automatically exported to IUCLID (International Uniform Chemical Information Database European).

**Source:** [http://echa.europa.eu/doc/press/na\\_10\\_38](http://echa.europa.eu/doc/press/na_10_38)

### **The Chemical Industry as Providers of Solution**

CEFIC, which represents the European chemical industry, held an event in Antwerp demonstrating the strategic importance of the Chemicals sector to the European union. The Belgian EU Presidency (which lasts until the end of 2010) chose the chemical industry as a theme of particular importance for its Presidency. The objective of the conference was to formulate concrete recommendations and provide input for the Competitiveness, Research and Industry Council as well as for the Internal Market Council, both taking place during the Belgian Presidency of the EU. A summary webcast and further information can be found on the CEFIC website.

**Source :** <http://www.cefic.be>

### **EMA and US FDA cooperate on Joint GMP inspection programme**

The European Medicines Agency (EMA) and the Food and Drug Administration of the United States of America (US FDA) are seeking potential candidate companies for a joint GMP inspection pilot programme for manufacturers of medicinal products. Companies that have submitted in parallel two equivalent marketing authorisation applications for the same medicinal product to both the EMA and the US FDA can request to participate in the pilot programme for joint pre-approval inspection should such an inspection be considered necessary by both agencies. The overall objective is to see whether greater international collaboration can help to distribute inspection capacity allowing more manufacturing sites to be monitored and reducing unnecessary duplication.

**Source:** <http://www.ema.europa.eu/ema/index>

### **Matthias Beller wins new 'European Sustainable Chemistry Award'**

Matthias Beller has been chosen as the first winner of the European Sustainable Chemistry Award – an initiative launched in 2010 by the European Association for Chemical and Molecular Sciences (EuCheMS). The 48 year-old chemist will be honoured during the 3rd EuCheMS Chemistry Congress in Nürnberg, Germany during the Congress opening ceremony on Sunday 29 August 2010. Professor Dr Matthias Beller, Director of the Leibniz Institute for Catalysis in Rostock, Germany (LIKAT), is being recognised for his exceptional research in the field of homogeneous catalysis. His main research focus is on investigating the environmentally sustainable conversion of small molecules into recyclable or reusable materials. He was selected as the first winner of this 10,000€ Award from a field of 21 highly competitive nominations.

**Source:** <http://www.euchems.org/News/ESCA2010.asp>

## **CHEMICALS UPDATE**

### **Bisphenol A and baby bottles: challenges and perspectives**

Bisphenol A (BPA) is extensively used in the synthesis of plastics and resins concern has arisen because of its widespread consumer exposure through various products coming in contact with food, such as baby bottles or food cans. Despite several risk assessment studies performed over the last ten years by different regulatory bodies worldwide, there is so far no agreement about the impact of BPA on human health. The review report "Bisphenol A and baby bottles: challenges and perspectives", published by the JRC Institute for Health and Consumer Protection (IHCP), provides an overview of the issues at the base of the on-going debate and highlights some areas of uncertainty, which may be the subject of future investigations.

**Source:** <http://ec.europa.eu/dgs/jrc/index.cfm?id=2820>

### **Furan in Food**

The European Food Safety Authority (EFSA) has issued an update of results on the monitoring of furan levels in food, in order to allow for a better estimate of dietary exposure to furan. The European Commission asked Member States to collect data on furan levels in heat-treated commercial food products. A first report on these findings was published by EFSA in 2009 and the current update brings additional data to the compilation. The report says that a comprehensive risk assessment will require more detailed exposure assessment data, as well as better information on the toxicity of furan.

**Source:** <http://www.efsa.europa.eu/en/press/news/datex100730b.htm>

### **Food additives – Azo dyes**

The European Food Safety Authority's (EFSA) scientific Panel on additives has assessed the safety of the red food colouring Amaranth (E123), completing the re-evaluation of all azo dyes authorised for use in the European Union. Amaranth is a red azo dye colour which can be used to colour foods such as aperitif drinks and fish roe. After reviewing all available toxicological data, the Panel concluded that the colour is not genotoxic (does not damage the genetic material of cells), nor carcinogenic. The Panel set an Acceptable Daily Intake (ADI) for the substance of 0.15 mg per kg body weight per day. The Panel noted that the mean exposure of adults is far below the ADI. Children's exposure was estimated to be around 30 times lower than the ADI. The study was carried out at the European Commission's request, to re-evaluate the safety of all food additives authorised for use in the EU. In particular, the European Commission asked EFSA to prioritise the assessment of azo dyes colours following publication of a study suggesting a possible link between certain

mixtures of colours (including five azo dyes) and the preservative sodium benzoate and hyperactivity in children.

**Source:** <http://www.efsa.europa.eu/en/press/news/ans100726.htm>

### **Presence of PCBs in Food and Feed**

In 2002, the European Commission issued a list of actions to be taken to reduce the presence of dioxins and Polychlorinated biphenyls (PCBs) in food and feed and recommended that Member States monitor the situation. The European Food Safety Authority (EFSA) has published a report on the levels of non dioxin-like polychlorinated biphenyls in food and animal feed. The EFSA recommends continuous random testing of a sufficient number of samples in each food and feed group in order to ensure accurate assessment and monitoring of the presence of PCBs in the food chain.

**Source:** <http://www.efsa.europa.eu/en/press/news/datex100730.htm>

### **Halons to be Phased Out**

The Commission has recently amended a regulation of halons. Halons are an ozone depleting substance and whilst it was accepted that their use was critical in some products, such as, fire extinguishers, a review has shown that, with few exceptions, halons are no longer necessary to meet fire protection needs in new designs of equipment and new facilities and that alternatives are now routinely being installed. The use of halons will be phased out over the coming years.

**Source:** <http://eur-lex.europa.eu/LexUriServ>

### **Update on the ongoing benefit-risk review of Avandia, Avandamet and Avaglim**

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP), part of the European Medicines Agency announced that it is currently reviewing the rosiglitazone-containing antidiabetes medicines Avandia (rosiglitazone), Avaglim (rosiglitazone/glimepiride) and Avandamet (rosiglitazone/metformin hydrochloride), from Smithkline Beecham Ltd, to determine the impact of new data, from recent publications on the risk of cardiovascular problems, on the benefit-risk profile of these medicines. While the Committee is reviewing all available data, prescribers in Europe are reminded to strictly follow the produce information.

**Source:** <http://www.ema.europa.eu/ema/index.jsp?curl=pages>

### **Positive opinion for Twynsta adopted**

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for Twynsta (telmisartan/amlodipine), from Boehringer Ingelheim International GmbH, intended for the treatment of essential hypertension. The review for Twynsta began on 23 September 2009 with an active review time of 210 days.

**Source:** <http://www.ema.europa.eu/ema>

## FUNDING

### **SMEs - Adverse Drug Reaction research through the European Commission's 7th Framework Programme?**

The European Medicines Agency and the European Commission, DG Research, are considering organising a joint workshop on 13 September 2010 to raise awareness on the potential funding opportunities through the 7th Framework Programme for health research in 2011 and provide guidance to interested parties on the application procedure to be followed to facilitate applications from SMEs. The workshop will be confirmed in the event of sufficient interest i.e. receipt of a considerable number of pre-registrations.

**mailto:** [encepp\\_secretariat@ema.europa.eu](mailto:encepp_secretariat@ema.europa.eu).

The workshop is particularly intended for, but not limited to: Contract Research Organisations (CROs), service providers, academic spin-off companies, consultancies with a specific interest in the field of pharmacovigilance, pharmacoepidemiology, health outcome research, patient-reported outcomes, drug utilisation studies, etc. It is not intended for pharmaceutical companies (i.e. Marketing Authorisation Holders).

The 5th Health Call was published by the European Commission on 20 July 2010 (deadline for submission of proposals is 10 November 2010).

**Source:** <http://www.ema.europa.eu5>

### **FET Flagships – two to selected to be launched in 2013**

FET Flagship Initiatives are proposed to be visionary, science-driven, large-scale research initiatives, that take a multidisciplinary approach to ICT future and emerging technologies. FET Flagships will aim to generate a wave of technological innovation and economic exploitation, ideally in a variety of areas and sectors, and would carry an important societal impact. At a recent meeting in Brussels, stakeholders discussed the future of the flagships and three parallel sessions were organised including sessions on 'Biological-Material ICT confluence' and 'New Paradigms for Computing and Engineering'.

**Source:** <http://cordis.europa.eu/fp7/ict>

### **24th September deadline - COST Open Call**

COST is an intergovernmental framework for European Cooperation in Science and Technology. COST funds different sorts of networking activities including: meetings, conferences, short term scientific exchanges and outreach activities. Proposals that play a precursor role for other European programmes are particularly welcome. Applicants are asked to select one of the nine broad research domains, including the domain dedicated to 'Chemistry and Molecular Sciences and Technologies', however, inter-disciplinary proposals are welcome and will be assessed separately. The deadline is 24<sup>th</sup> September and 'Actions' will be selected in a two stage process. A financial allocation for each action is around €100,000 over an average period of 4 years, each action must include a minimum of 5 COST countries. For further information on COST go to [www.cost.eu](http://www.cost.eu)

**Source:** <http://eur-lex.europa.eu/LexUriServ>

## Open Consultations

Public consultation on Addictiveness and Attractiveness of Tobacco Additives Public Health, deadline 5<sup>th</sup> September 2010

Public consultation on Definition of "Nanomaterial" Public Health, deadline 5<sup>th</sup> September 2010

Public consultation on the Raw Materials Initiative Enterprise, deadline 19<sup>th</sup> September 2010

**Source:** [http://ec.europa.eu/yourvoice/consultations/index\\_en.htm](http://ec.europa.eu/yourvoice/consultations/index_en.htm)

## Forthcoming Events

### August

**29<sup>th</sup> August – 2<sup>nd</sup> September**, 3rd EuCheMS Chemistry Congress, Chemistry - the Creative Force, Nürnberg / Germany

### September

**7 and 9 September**, 'Industrial Technologies', focusing on nanotechnology and nanosciences. Belgian Presidency programme. <http://www.industrial-technologies2010.eu/>

**14 September**, Conference on KBBE, Knowledge Based Bio-Economy – Cooperation area; there will be three main topics: feedstocks for the bio-economy; innovative bio-based products and innovative food production. <http://www.kbbe2010.be/>

**15 September**, High Level Group on Chemicals Industry Workshop

**24 September**, Researchers' Night

**23 and 24 September** – 'Soil, Climate Change and Biodiversity - where do we stand?' jointly organised by the Commission Directorate-General for the Environment and the Joint Research Centre



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