DELEGATION AGREEMENT ON

THE EUROPEAN UNION OBSERVATORY FOR NANOMATERIALS AND THE EUROPEAN UNION CHEMICAL LEGISLATION FINDER

[the contractual provisions are left out here]

ANNEX I – DESCRIPTION OF THE ENTRUSTED TASKS

1) The European Union Observatory for Nanomaterials

The Commission entrusts ECHA with the creation, management and maintenance of the European Union Observatory for Nanomaterials Observatory (referred to in this Annex as "Observatory").

Following a commitment made in the Second Regulatory Review on Nanomaterials (Commission Communication COM(2012) 572 of 3.10.2012) the Commission has carried out an Impact Assessment (IA) on transparency measures for nanomaterials. Based on the outcome of the IA, the preferred option to increase transparency and availability of information regarding nanomaterials is the setting up of a European Union Observatory for Nanomaterials, which was identified as the most efficient and proportionate measure.

The Observatory is part of other measures announced in the Second Regulatory Review on Nanomaterials intended to improve regulation on nanomaterials. This includes envisaged modifications in some of the REACH Annexes and a review of the definition of nanomaterials, on which the Commission plans to come forward with relevant proposals shortly. Together with progress in other legislative areas, these initiatives will provide important information for the work of the Observatory.

The main aim of the Observatory is to give objective and reliable information on markets and safety aspects of nanomaterials in the EU market. The Observatory will collect, analyse and review available information from a wide range of sources, and complete this information by external studies to fill specific data gaps (e.g. new market studies and surveys) on nanomaterials on the market. A major part of the Observatory shall be devoted to presenting information on nanomaterials, their uses and their safety in a clear and user-friendly way to business, workers, consumers and authorities. One of the objectives is to improve the business environment for EU companies and SMEs in particular with regard to access to information on the use and safety of nanomaterials.

ECHA is seen as the most suitable host for the Observatory because of the synergy between the tasks of the Observatory and ECHA's tasks of managing and evaluating data arising from the implementation of REACH[1], CLP[2] and BPR[3], which can provide part of the data to be used for the Observatory. Another important synergy derives from ECHA's experience in informing the public about chemical substances, for which it has developed effective communication tools. In addition, ECHA possesses the necessary expertise and independence to carry out appropriate validation and verification of data before incorporating it into the Observatory.

Despite the above-mentioned synergies, the Observatory is outside ECHA's core tasks because the planned tasks go beyond the scope and purpose of REACH, CLP and BPR. The Observatory shall provide information on all nanomaterials, including those which are outside the scope of REACH, CLP and BPR (e.g. cosmetics, and to an extent, food and medicines). Uses and applications shall be explained at a level of detail which clearly goes beyond the

[1] Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1.

[2] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, OJ L 353, 31.12.2008, p. 1.

[3] Biocidal Product Regulation (EC) No 528/2012, OJ L 167, 27.6.2012, p. 1.

information to be expected under those pieces of legislation and will require studying of other information sources such as market studies, national registries etc. It shall also cover other policy areas which are regulated by specific legislation (e.g. workers health and safety at work [4, 5, 6]).

With respect to hazards and risks of nanomaterials, the main purpose shall be to communicate existing information to the public. The information presented by the Observatory shall be consistent with Union policies.

Where the use of nanomaterials is subject to pre-market authorisation under Union legislation, for instance when they are used in food, food contact materials, cosmetics, medicines, or where other assessments concerning their hazards and risks have been made under the political responsibility of the Union, the activities of the Observatory shall not interfere with the scientific assessment of the competent EU agencies, their risk communication, specific competence, and the risk management measures taken by the Commission. In particular, the Observatory shall provide summaries or links to scientific opinions or assessments of the hazards and risks in cooperation with the relevant agencies. It shall report and explain risk management decisions relevant to these substances following consultation with the relevant Commission Services.

Where data concern the hazard and risk evaluation under competency of other agencies, it shall rely mainly on the data made available by these agencies. The Observatory shall clarify that the evaluation of specific data for the purpose of authorisation decisions is a matter for those agencies, using their respective criteria to ensure the scientific robustness and adequacy of relevant studies for the purpose of risk assessment. This shall not affect the use and integration of general research data by the Observatory, for instance from EU research projects, applying the necessary care in describing the scientific value and if appropriate limitations of the data presented.

The information presented by the Observatory shall be presented in a neutral manner that does not complement or provide an alternative assessment of the hazards and risks related to such regulated nanomaterials under the competence of other Union agencies.

In particular, ECHA will carry out the following tasks:

(a) Collection of data from other information sources

The Observatory shall systematically extract information on nanomaterials, their markets and safety from available information sources, link it to other relevant information and present it in a structured manner.

The Observatory shall use:

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[4] Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), OJ L 183, 29.6.1989, p.1

[5] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 131, 5.5.1998, p.11

[6] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), (codified version), (Text with EEA relevance), OJ L 158, 30.4.2004, p.50

data already collected through REACH registration dossiers (for substances with nanoforms that are subject to the registration duties of the REACH Regulation);

data available about the use of nano-materials in authorised regulated products (e.g. foods, food contact materials, pesticides, biocides, medicines) as made available in scientific opinions and in Commission decisions, databases, union lists and registries;

notifications of nanomaterials in cosmetic products (through the Cosmetics Regulation);

data collected through national registration or notification systems;

available market studies;

in agreement with other EU Agencies and subject to legal requirements, data held by other EU Agencies;

information from industry, workers and consumer associations;

information available on the Internet;

information on hazards and risks of nanomaterials from sources such as ECHA's databases, research projects (7th EU Research Framework Programme, Horizon2020), general scientific literature, scientific opinions in the context of cosmetics, food contact materials, workers health and safety at work (such as that available in the relevant webpage of the EU-OSHA[7]);

any other information sources deemed relevant and/or useful.

ECHA shall develop an appropriate system for checking the relevance, reliability and validity of the information contained in the Observatory. Where relevant, links to the information sources shall be provided. Where relevant, ECHA shall cross-check information with other EU Agencies such as EFSA, EMA and EU-OSHA as well as the Commission.

This information shall be linked, summarized and interpreted[8] with a view to giving a clear and objective picture on nanomaterials, their uses and applications, as well as their hazards and risks. Where applicable, this information shall be consistent with relevant scientific assessments, authorisation decisions etc.

The Observatory shall integrate and expand, as appropriate, the ongoing work on the JRC web platform on nanomaterials. The Observatory shall also build upon other relevant tools, such as the nanomaterial registry by RTI International[9] and the Wissensplattform Nanomaterialien.[10] Collaboration (sharing data or interlinking) with other international initiatives shall also be sought.

[7] https://osha.europa.eu/en/themes/nanomaterials

[8] 'Interpretation ' is understood as explaining the data to the public, and not in the sense of providing a scientific opinion on hazards and risks related to regulated nanomaterials, particularly where this is the competency of other EU agencies or bodies.

[9] https://www.nanomaterialregistry.org/

[10] http://nanopartikel.info/cms

Subject to availability of resources, the Observatory shall harvest data and results from existing and ongoing scientific studies and research projects[11], through appropriate means such as hosting, maintaining and updating relevant tools and databases, and ensure research data sustainability. Where appropriate, this can be complemented through arrangements providing additional financing.

Under the funding provided for the first financial year, and respecting the timelines for implementing tasks under the funding for the first financial year, ECHA shall:

integrate the content of the JRC web platform, as amended by ongoing projects, in the Observatory;

analyse and decide on options for the necessary IT developments to support the Observatory;

establish the necessary planning and procedures for the systematic extraction of relevant information on nanomaterials, their markets and safety from available information sources;

set up structures and mechanisms to check the relevance, reliability and validity of the information;

establish general rules and procedures for the use of confidential information sources available in ECHA, in particular the extraction of non-confidential summary information from confidential information; where this concerns data owned by a third party, relevant rules on the extraction of non-confidential summary information shall be agreed with the third party.

liaise with the owners of other information sources, discuss and agree the best way of co-operating and exploiting synergies between various existing information tools, including as a minimum relevant projects under the European Commission's 7th Research and Innovation Framework Programme, Horizon2020, the Cosmetics Notification Portal, the national notification schemes in France, Denmark and Belgium, the nanomaterial registry by RTI International, the DaNa Wissensplattform and other EU Agencies;

in consultation with the responsible Commission services, decide whether and how other existing information sources shall be integrated in the Observatory.

integrate summary information from the analysis of relevant REACH registration dossiers on nanomaterials.

(b) Launching new case studies and reviews

The Observatory shall complement available information by initiating or procuring relevant market studies and scientific information analyses (curating data) on nanomaterials. Such studies shall allow filling identified knowledge gaps, in any area that is considered to be relevant for the public debate on nanomaterial safety. However, the choice of studies should reflect the Observatory's role of linking data and giving overview information, and only in exceptional, duly justified cases include fundamental research.

[11] In particular from, but not limited to, projects funded under the 7th EU Research Framework Programme and Horizon 2020 (see www.nanosafetycluster.eu)

Possible[12] subjects for studies could e.g. cover: analysis of the emerging market on graphene; analysis of producers and uses of nanosilver; sector analysis of uses of nanomaterials; literature analysis of key scientific issues such as bioaccumulation of nanoparticles in cells; etc.

Under the funding provided for the first financial year, and respecting the timelines for implementing tasks under the funding for the first financial year, ECHA shall conduct or buy at least one relevant study. The Commission shall be consulted on the choice and, where appropriate the terms of reference of studies.

(c) Communication of information on nanomaterials, their uses and their safety to target audiences

The Observatory shall develop tools to communicate information on nanomaterials, their uses and their safety to the general public, including consumers and workers, as well as their organisations, authorities and decision-makers in a user-friendly, understandable and targeted way. ECHA's general translation policy will be applied subject to availability of funding, including translation of webcontent targeted to non-expert audiences to all EU languages. This shall in particular, but not only, build on the results of the work under tasks (a) and (b) and explain:

What nanomaterials are;

where and in which products they are used;

what this means in terms of hazards and risks for consumers and workers, as well as for the environment;

Under the funding provided for the first financial year, and respecting the timelines for implementing tasks under the funding for the first financial year, ECHA shall:

Establish a plan how the Observatory will be integrated as part of ECHA webpages. The plan shall consider how to best balance clever linking to nano content in other segments of ECHA's website and development of new specific content;

establish webcontent via a microsite targeted mainly at consumers and workers to provide easily understandable information about nanomaterials (if appropriate as part of a microsite covering also other topics on chemicals), their uses and risks. The microsite shall be part of the existing ECHA domain and shall be designed and its content drafted in a way that interested consumers and workers with an average education are able to understand the information. It shall also contain relevant summary information for consumer and worker organisations, and provide links to further in-depth information. The approach to and content of the microsite shall be discussed with relevant stakeholders and their organisations as well as operators of similar websites;

develop a communication strategy to attract the interest of citizens, workers and decision makers, including press activities, organising and participating in events, the use of social networks, promoting links in other relevant websites, etc.;

[12] The subjects mentioned are for illustrative purposes only, and do not represent any concrete plan of launching such studies.

investigate options to develop or integrate communication tools that can raise the interest of website visitors and that can help website visitors to better understand the uses and risks of nanomaterials;

set up a procedure for the general public interested in receiving further information on nanomaterials and in giving feedback on the content of the Observatory.

For the following financial years, ECHA shall, in preparing the annual work programme for a the relevant financial year, prepare a proposal for activities to be implemented under the funding for that financial year, including clear deliverables and indicators for their implementation, which shall also be based on the use of the tools by stakeholders. On the basis of this proposal, ECHA shall agree with the Commission a work programme for the relevant financial year, which shall be included as a section into ECHA´s annual work programme.

ECHA's operational work under REACH (e.g. analysis of REACH registration dossiers), CLP and BPR with respect to relevant information on nanomaterials shall be part of the regular ECHA activities, and shall not be covered by funding under this agreement.

Activities funded under this agreement shall be clearly identified as being part of the European Union Observatory for Nanomaterials, and a visible logo for the Observatory shall be applied.

ECHA shall invite Member States and stakeholders to contribute to the work of the Observatory, including by providing complementary information, by contributing to the planning of activities and by giving feedback on the operation of the Observatory.

2) The European Union Chemical Legislation Finder

The Commission entrusts the ECHA to undertake a feasibility study with a view to creating a 'EU Chemical Legislation Finder' to improve the business environment for EU companies and SMEs in particular with regard to access to information on regulation applicable to a given chemical substance.

Currently, a given chemical substance can be subject to several EU policies/legislations pursuing different objectives (REACH, biocides, pesticides, cosmetics, fertilisers, drug precursors, explosives, pyrotechnics, detergents, worker protection, toy safety etc). This information is however not accessible by substance. To find exhaustive information on a given substance, it is necessary to browse and understand all existing legilsations. This renders the access to information on a specific substance burdensome and costly. This is in particular the case for SMEs that have to deal as producers or downstream users with a limited number of chemical substances but use them for different applications covered by different legislation. The creation of an EU Chemical Legislation Finder would address this issue.

Considering that compliance with EU legislation is often mandatory in order to sell and distribute substances, this initiative facilitates access to markets for SMEs.

The action to be financed consists in a feasibility study prior to the definition and implementation of a project, in particular with regard to the scope of the EU legislation to be covered, the potential market needs, the interoperability of data sources, the service level to be considered, aspects of its organisation and operation, the financial needs for the set-up and the update of IT solution and related services.

The study will:

Identify the relevant sources and how they relate to chemical substance;

analyse how the information can be linked, presented and searched;

identify interoperability options also looking into existing models and experiences;

prepare scoping scenarios and related impacts.

The study will provide the groundwork for the solution architecture and the high level planning of the implementation. An incremental approach to delivering a viable service in stages will be considered, if suitable.

The study will engage stakeholders (Commission, Industry associations) in the requirements extractions and in the validation of the scoping scenarios.

No similar measures have been developed at EU level so far. Private tools exist but are quite expensive for SMEs.

The Chemical Legislation Finder will also contribute to building confidence in the public at large, as it contributes to public understanding of how chemical substances are regulated at EU level.

The task of conducting the feasibility study with a view to creating an EU Chemical Legislation Finder falls outside the scope of the mandate of the ECHA. ECHA is seen as the most suitable body to conduct the feasibility study with a view to creating an EU Chemical Legislation Finder because of the synergies between its tasks in managing and processing data arising from the implementation of REACH[13], CLP[14], BPR[15] and PIC[16]. In addition it has already relevant expertise in processing and informing the public about chemical substances for which it developed effective IT tools.

[13] Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396, 30.12.2006, p. 1.

[14] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures, OJ L 353, 31.12.2008, p. 1.

[15] Biocidal Product Regulation (EC) No 528/2012, OJ L 167, 27.6.2012, p. 1.

[16] Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals, OJ L 201, 27.7.2012, p.60.

ANNEX II – ESTIMATED BUDGET FOR THE ENTRUSTED TASKS

1) The European Union Observatory for Nanomaterials

The indicative budget for the period 2016-2020 is a maximum of EUR 3.200.000, with annual instalments under the Work Programme of COSME for 2016 of EUR 800.000, and of EUR 600.000 for each of the financial years 2017, 2018, 2019 and 2020.

ECHA shall allocate the budget in the best possible way to achieve the objectives and tasks of this agreement, including, where necessary, by staff recruitment. As a minimum 10% of the annual budget shall be spent on each of the subtasks a to c mentioned in Annex I.

The additional staff in ECHA is a maximum of three contract agents. The duration of their contracts should be aligned with the duration of the project and in any case not go beyond 2020. No establishment plan posts can be foreseen for the Observatory.

2) The European Union Chemical Legislation Finder

The indicative budget for 2016 is a maximum of EUR 100.000 for conducting a feasibility study for an EU Chemical Legislation Finder.

The Union contribution shall cover the costs of the feasibility study through a procurement procedure.

ANNEX III – MODEL MANAGEMENT DECLARATION

[Annex III is left out here]

ANNEX IV – MODEL TRANSFER OF FUNDS AGREEMENT

[Annex IV is left out here]