MECHANISM FOR EXCHANGING INFORMATION BETWEEN MEXICO – US ON REGULATORY MATTERS FOR NANOTECHNOLOGIES

Mexican Proposal

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| Introduction | In the HLRCC (*High Level Regulatory Cooperation Council*) framework, the essential importance of an effective and timely exchange of information on regulatory matters dealing with nanotechnology, including nanomaterials, aimed to achieve an effective cooperation between Mexico and US has been detected. Regulatory cooperation can increase economic growth in each country; lower costs for consumers, businesses, producers, and governments; increase trade in goods and services across our borders; and improve our ability to protect the environment, health and safety of our citizens. (Ref: *Work Plan for the United States and Mexico - High Level Regulatory Cooperation Council*).  The Work Plan includes, among others, the “*Creation of a mechanism for exchanging information between the U.S. and Mexico on regulatory matters for nanotechnology*.” |
| General  description | The proposed mechanism encompasses an element devoted to facilitate the exchange of information among regulators of both countries, as well as research and development, and academic institutions, and other interested parties; also, a technology monitoring element is included.  The main features of the proposed mechanism as a whole include:   * Dynamic * Pertinent * Focused * Effective * Agile * Active monitoring * Fair * Compliant with existing regulations, including those related to data confidentiality.   Information on matters related to regulations for nanotechnologies to be exchanged comprises, with no exclusion of any other regarded as relevant:   * Actual regulations. * Initiatives for new regulations. * Modifications of existing regulations to include nanotechnologies issues. * Modifications of existing regulations. * Follow up to the processes to produce, approve, implement, modify or cancel regulations. * Contents of the approved regulations and supporting information. * ~~Extraordinary findings on the conformity assessment of the regulations.~~ * Data on engineered nanomaterials or products containing them traded or to be traded between the two countries.   The technology monitoring element is aimed to detect and share findings on actual or potential risks to health, safety and the environment due to applications of nanotechnologies. The goal is to have an updated system containing results supported by scientific evidence, related to risks to health and damage to the environment due to nanomaterials or products containing them, along their life cycles since their development to their deposition. Such findings may include confirmation or rejection of risks, or intermediate levels, and toxicological and ecotoxicological results.  Anyway, the activities related to this mechanism shall be always compliant with the legal prescriptions in each country. |
| Facilitation of the exchange of information | The facilitation of the exchange of information would become the responsibility of government agencies, preferably the actual contact points for nanotechnologies, namely the Executive Office of the President of the United States, and the General Direction for Standards of the Ministry of Economy (Dirección General de Normas de la Secretaría de Economía), on behalf of the US and México respectively. The assigned agencies should keep direct communications with the government agencies that provide the required information in each country.  The information exchange comprises voluntary contributions of mutual interest as well as specific requests from both countries.  The implementation of this element includes, in each country:   1. Create a Directory of Regulatory Agencies and Involved Organizations on Nanotechnology, with the corresponding contact points either by sector or by topic. 2. Assess how appropriate are the actual levels of communication and exchange of information among the involved parties, check them periodically, every six months as an option, and enhance them as needed. 3. Promote good practices at communicating, like to issue immediate acknowledges of reception and to add copies to the involved parties. 4. Ensure that prescriptions on confidentiality are applied, as required by the country providing the information. 5. Try timely responses to requests of information, either providing it, or offering valid arguments explaining the delay or rejection to deliver it. 6. Communicate to the involved parties any change in the contact points.   The responsible agencies for this element would be the General Direction for Standards of the Ministry of Economy (Dirección General de Normas de la Secretaría de Economía) in Mexico, and that regarded by the US as convenient, probably the Office of Information and Regulatory Affairs. |
| Technology monitor | The objective of this element would be to offer the possibility of fast and reliable consultation, aimed to regulatory purposes mainly, by means of a data base with findings related to risks to the health, safety and environment derived from the use or exposition to engineered nanomaterials, regardless of the way such exposition occur and in any of the stages of their life cycle.  The database would be fed with the contributions of regulators, research and development institutions, academy, and other interested parties in US and Mexico, and from other countries as well.  Before feeding it to the database, the reliability of all of the information should be assessed, based in objective criteria such as its publication in indexed journals or in documents issued by recognized institutions should be assessed. Designated agencies by the authorities in each country would take responsibility for such assessment. The received information that become regarded as pertinent, but lacking enough scientific support to rate it as reliable, will be put in a special section of the database labeled for the purpose. This information may be relocated as reliable when sufficient supporting evidence comes in.  The database would be composed by one part in each country, that would manage its own part and provide access to the agencies and organizations within the Directory of Regulatory Agencies and Involved Organizations on Nanotechnology, under the applicable requirements of confidentiality.  The database would be managed by the agencies designated for this purpose by the authorities of the respective countries.  The implementation of this element would include:   1. Agreement between the two countries for the database structure, the type of contents and the software design. 2. Implementation of the corresponding software and its administration by each country, including the necessary responsibilities. 3. Agreement between the two countries the mechanisms for the data reliability assessment and set them up by each country. 4. Agreement on the ways to access the database. |
| Calendar | The complete implementation of each of the two elements is expected to last six months after reaching agreement between the two countries. |

This proposal has been produced by the HLRCC Working Group – nano, with representatives of:

* Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) - Dirección Ejecutiva de Evidencia de Riesgo, Comisión de Evidencia y Manejo de Riesgos, Dirección Ejecutiva de Operación Internacional
* Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA) - Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) - Subdirección de Certificación y Reconocimiento, Dirección General de inocuidad Agroalimentaria, Acuícola y Pesquera
* Secretaría de Economía – Dirección General de Normas
* Secretaría de Medio Ambiente y Recursos Naturales (SEMARNAT) - Instituto Nacional de Ecología.
* Centro de Investigaciones Interdisciplinarias en Ciencias y Humanidades – Universidad Nacional Autónoma de México
* Centro de Investigación en Materiales Avanzados (CIMAV)
* Centro de Nanociencias y Micro y Nanotecnologías – Instituto Politécnico Nacional
* Centro Nacional de Metrología (CENAM)
* Red Nacional de Nanociencias y Nanotecnología del CONACYT

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