

(Innovation for the pathway to nano-regulation)
The role of European and national authorities governing nanotechnologies

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Regulating and managing the potential impacts of nanotechnologies on health, environment, employment, economy and society has been a challenging debate. The intrinsic dynamics, policy difficulties, stakeholders' debates, scientific emerging issues and the uncertainties that arise with the nanotech, urge to undertake an innovative pathway for nanotechnologies' governance, a change in the way new technologies have been addressed so far.

The current diverse and multiple initiatives need a guiding thread, this means bringing them together to give responses to the real needs of the society, which are exposure assessment and traceability of nanomaterials and nano-products. If these issues are not primarily addressed, the governance for nanotechnologies will not make sense, it will not provide safe nanotechnologies.

In order to explore if current legislation work effectively a European regulatory review related to nanomaterials in chemicals, waste, air, water and workers safety regulations, is being conducted by the European Commission. [1] Possible changes of the legislation will take considerable time, this is why the governance needs to make available instruments of implementation that at the moment are still lacking.

For instance, identifying nanomaterials in the REACH registration dossiers is a challenging issue; so far it is up to the registrants to indicate the substance as a nanoform. Nanomaterials produced or imported below 1 ton per year are exempt of the Registration process under REACH. And the parameters defining information to be communicated in Safety Data Sheets and in the supply chain have not been developed for nanomaterials. A challenge for the European Commission is making REACH work properly for nanomaterials.

The number of products containing nanomaterials on the global market is unknown; many products incorporate nanomaterials that have been developed with some kind of assessment of safety and risks of their nano-specific features, but others are produced even without any. Surprises will appear by the time there are clear figures of what products have been produced using nanotechnologies, which ones contain nanoparticles and which release them. Furthermore there are no updated figures on the risks to human health and the environment. This is the reason why more research allocated to health and safety issues together with transparency and traceability of nano-products placed on the market is of key importance.

The role of Member states is crucial on moving in the direction of concrete governance. It is remarkable how several countries like Belgium, France, Germany, Italy and the Netherlands are pursuing activities related to reporting mandatory schemes of articles containing nanomaterials [2]. The driver of these initiatives is underpinning traceability, market surveillance and securing knowledge for better risk prevention and for improvement of the legislative framework. To improve the situation, the harmonization of the data-bases is desirable. This measure has been recommended by the Council of Europe to the Commission [3].

In terms of the workforce scenario, the European Trade Union Confederation has contributed pointing out elements of the European policy that it sees as essential to responsible development of this emerging technology [4]. The key concerns are to deal with a shift of employment and to cope with the introduction of the new technology and significant changes in work processes and working conditions that could disrupt the working environment.

Exposure to humans can be significant while working with nanoparticles. There are no figures of workers exposed to nanoparticles, to which ones, and in which quantities and processes. A second governance challenge is mapping the working force related to them, who is exposed to what type of substances, identifying those activities which imply exposure. In addition, long term medical surveillance. Exposure registries can build on further epidemiological studies and risk management. [5]

In short, the common element of these approaches to governance is to pursue the collaboration as a necessary to achieve effective governance. At the same time, it builds reflective capacity of the actors and stakeholders involved in this process.

References

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- [5] Schulte, A, **Medical surveillance, exposure registries and epidemiologic research for workers exposed to nanomaterials** (2010) Toxicology, Volume 269, Issues 2-3.