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France might take the lead on nanotechology regulation

The French government has proposed legislation which if enacted would, for the first time in the EU, start to regulate the manufacture, import or marketing of nanoparticle substances. If this proposed legislation is adopted, this will create many challenges for corporations, regulators and the French government, as well as potentially raise questions of compatability of the legislation with EU law.

The French Proposals form part of a very broad environment project referred to as the Grenelle project, which was launched in 2007. The project splits into two proposed laws, Grenelle 1 and 2. Grenelle 1 has completed its first reading and is currently before the National Assembly for its second reading. It is intended to establish the general principles, whilst Grenelle 2 is intended to provide details.

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Article 37 of Grenelle 1 currently includes the following principle:

"L'État se donne pour objectif que, dans un délai de deux ans qui suit la promulgation de la présente loi, la fabrication, l'importation ou la mise sur le marché de substances à l'état nanoparticulaire ou d'organismes contenant des nanoparticules ou issues de nanotechnologies fasse l'objet d'une déclaration obligatoire, relative notamment aux quantités et aux usages, à l'autorité administrative ainsi qu'une information du public et des consommateurs."	"The State sets itself the goal that, within two years after the law is adopted, the manufacture, importation, or marketing of nanoparticle substances or organisms containing nanoparticles or the product of nanotechnology will become the object of obligatory declaration, notably on quantities and uses, to the administrative authority as well as information to the public and to consumers."

Grenelle 2 was on 12 January 2009 proposed by France's minister for Ecology, Energy, Sustainable Development and Territorial Development, Mr. Jean-Louis Borloo to the National Assembly, so it is still very early in the legislative process. However, the details of the proposal on nanotechnology are informative. They are contained in Article 73:

- An amendment to the French "Environmental Code", by inserting a new Chapter III : "Prevention of health and environmental risks due to exposure to "nanoparticle substances" which includes the requirements that:
  - Any person that manufactures, imports or places on the market nanoparticle substances (including for the purpose of research), must periodically declare to the administrative authority the identity, quantities and uses of the substances.
  - Information related to the identity and uses of these nanoparticle substances shall be publicly available under conditions to be established under the law.
  - Any person that manufactures, imports or places on the market any nanoparticle substances are required, at the request of the administrative authority, to transmit all available information relating to the hazards related to these substances as well as the likely exposure to these substances.
- Amendments are also proposed to the French "Public Health Code" and the "Rural Code" to the effect that the rules contained in the Environmental Code relating to nanoparticle substances also apply to the use of such substances as components in medicinal products for human or veterinary use and cosmetics covered by the Public Health Code, and as components in phytopharmaceutical products (preparations and products containing genetically modified organisms for use on plants) covered by the Rural Code.

The French proposals do not occur in a vacuum. On 19 January 2009 the European Parliament's Committee on the Environment, Public Health and Food Safety issued a draft Report on the regulatory aspects of nanomaterials. In the EP Report is a call for an EP Resolution on regulatory aspects of nanomaterials, including the following:

- Calls on the Commission to propose reviews of all relevant legislation by the end of 2009 to fully implement the principle "no data, no market" for all applications of nanomaterials in consumer products or in products leading to discharges to the environment.

- Reiterated call for labeling of consumer products containing nanomaterials.
- Calls for the urgent development of adequate testing protocols to assess the hazard of, and exposure to, nanomaterials over their entire life cycle, using a multi-disciplinary approach.

The same day, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks adopted its opinion on "Risks Assessment of Products of Nanotechnologies". The final paragraph of the executive summary states:

"The health and environmental hazards were demonstrated for a variety of manufactured nanomaterials. The identified hazards indicate potential toxic effects of nanomaterials for man and environment. However, it should be noted that not all nanomaterials induce toxic effects. Arguably, some manufactured nanomaterials have been in use for a long time (carbon black, TiO2) and show low toxicity. The hypothesis that smaller means more reactive and thus more toxic cannot be substantiated by the published data. In this respect nanomaterials are similar to normal substances in that some may be toxic and some may not. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case by case approach for the risk assessment of nanomaterials is recommended."

It is notable that part of the stated policy reasoning behind both the French Proposals and the EP's Opinion is the so-called precautionary principle, which is expressly contained in Article 174 of the Treaty Establishing the European Community. The precautionary principle is of fundamental importance to policy and legislation in the EU. However, so is the creation and proper functioning of the common market (Articles 23 et seq.). Member State laws which hinder the proper functioning of the common market are in breach of EU law. Weighing one fundamental (the precautionary principle) against another (the common market) is a difficult exercise and the European Court of Justice has ruled against Member States in several cases where stated public health measures, which are detrimental to the common market, have been found not to be objectively justified. It is too early to tell whether the French Proposals would withstand scrutiny for compliance with EU law, because the bill is still being debated, but this potential scrutiny will have to be taken into consideration by French legislators.

For inquiries related to this Client Alert, please contact your usual product regulatory contact or Kiran Desai at kdesai@mayerbrown.com or Anna Gergely at agergely@mayerbrown.com or Sebastien Louvion at slouvion@mayerbrown.com

mayerbrown.com

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