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RISK REGULATORY OF NANO TECHNOLOGY

Risk Regulatory of Nano Technology

Presentation: Jan Holthuis, Partner BUREN Legal

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Content:
1. Nanomaterial Definition: Size or New Properties?
2. Which Principles to Apply to Possible Risk?: Unreasonable Risk / Precautionary Principle
3. Concluding Remarks

Regulatory Issues

- Lack of scientific data on nano-specific risks to Environment Health & Safety (EHS)
- Definitions of nanomaterial vary (non-active substances used for years in commercial products can fall in the scope of a nanomaterial definition. Is “size” or “new property” of material dominant?
- Different risk management measures and standards: “precautionary” or “unreasonable risk” principle?
- Shifting burden of proof to produce scientific evidence on risks to producers or government authorities?

SPECIAL NOTE: Number of nanomaterial patent applications increased 10-fold during the last 20 years, demonstrating a great potential for commercial applications but risk of overlapping or infringement of existing granted patents. Broad claims can lock-up huge areas of technology. Most patents owned by private companies in the US, Japan and Germany: China leading on scientific publications. Only 6% of nano patents is Agri & Food related.

Nanomaterial: Specific Properties?

EU Definition

REACH (Regulation No 1907/ 2006: Registration, Evaluation, Authorization and Restriction of Chemicals) REACH and **CLP (EU Regulation on Classification, Labelling and Packaging, Reg EC No 1272/2008)** play critical role in addressing EHS risks of nanomaterials by access to data (production above 1 ton/year)

REACH Definition of "Substances" that require registration:

> *"a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, by excluding any solvent which may be separated without effecting the stability of the substance or changing its composition".*

EC Recommendation defining Nanomaterial (2011/696/EU):

> *"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is 1 nm - 100 nm." (Commission deviated from 0.15% threshold advised by SCENIHR. But definition is subjected to continued review)*

Commission of European Communities (2008a):

> *"When an existing chemical substance, already placed upon the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include the specific properties of the nanoform of the substance". (if production or import quantity > 1 ton / year)*

US Definition

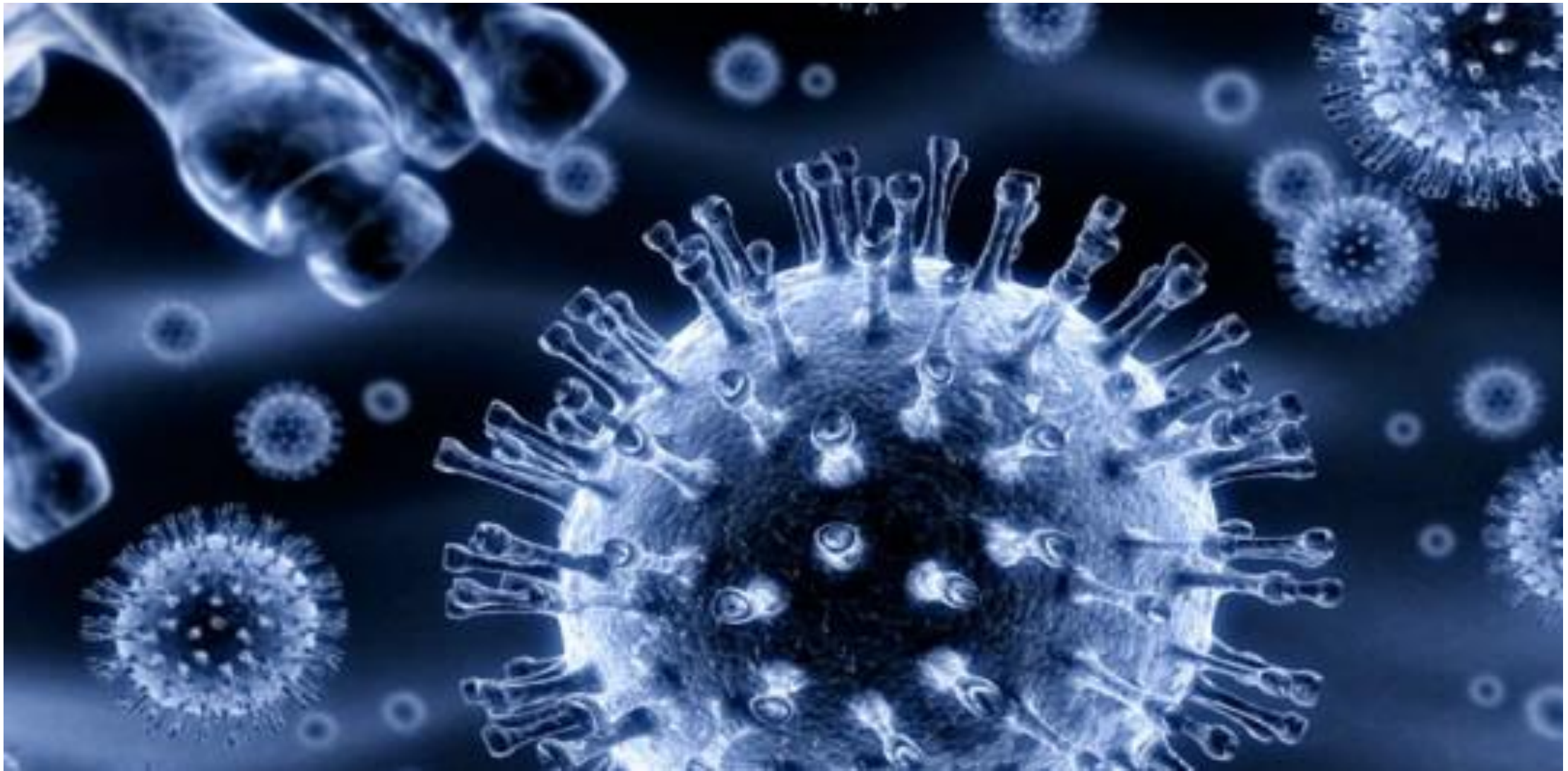
TSCA (Toxic Substances Control Act 1976)

Environmental Protection Agency (2008a: 2-3)

> *If a nanoscale material has the same molecule identity (same structural and compositional features, as apposed to physical and chemical properties, as a chemical listed on the TSCA Inventory), it is considered an "existing" chemical substance.*

- In other words: Even in the event the physical and chemical properties resulting from a size differ, EPA considers the two forms to be the same chemical substance. This position of EPA has proven been divisive
- Only "new" chemicals are automatically subjected to pre-manufacture notification (but EPA can issue a "Significant New Use Rule" = action regulator required)
- Information on regulatory actions and nanomaterials data suffer from broad claims of Confidential Business Information. EPA not manpower to challenge the large number of claims
- REACH has been described as a response to the failings of the TSCA

Which Principles to Apply to Possible Risk?



EU “Precautionary Principle”

- The Precautionary Principle is a strategy to cope with possible risks where scientific understanding is yet incomplete, such as the risks of New Technologies such as Nano Technology and Genetically Modified Organisms. EU has been unsuccessful in arguing before the WTO Dispute Settlement Body that the “precautionary principle” is a norm of international law.

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm. Morally unacceptable harm refers to harm to humans or the environment that is:

- *threatening to human life or health, or*
- *serious and effectively irreversible, or*
- *inequitable to present or future generations, or*
- *imposed without adequate consideration of the human rights of those affected.*

The judgement of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm. Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

EU Data Registration

- Evaluation of REACH: Continued lack of information on products containing nanomaterials. Databases rely upon non-verifiable declarations by producers. Some products marketed as "nano" may actually not contain nanomaterial, and products actually containing nanomaterial may escape the radar for lack of an obligation to label
- Only Biocides Product Regulation (EU Reg. 528/2012) has specific provisions to address active forms of nanomaterials (and uses the Commission nanomaterial definition). A separate dossier with all data requirements of a biocidal must be prepared as well as a dedicated risk assessment. Biocides are subjected to pre-market authorization (no labelling required for nano pesticides)
- In EU only France has adopted a mandatory registration scheme for nanomaterials. Denmark and Belgium are adopting equivalent mandatory schemes
- There are proposals that the threshold for nanomaterial registration is lowered to 10 kg (instead of present threshold of 1 ton/year)
- Presently there are no finalized and recognized testing guidelines for nanomaterial potential hazards

US “Unreasonable Risk” Principle

TSCA (Pub.L.No. 94-469, 2(b) 1976)

“Authority over chemical substances and mixtures should be exercised in such a manner as to not impede unduly or create unnecessary economic barriers to technical innovation while fulfilling the primary purpose of the Act to assure that such innovation and commerce in such chemical substances and mixtures to not present an unreasonable risk of injury to health or the environment”

- Activity or product can be regulated if causation between event and damage is proven (scientific uncertainty is not taken into account)
- Chemical substances are safe unless proven otherwise by the EPA
- US / Canada often criticize “precautionary principle” as unnecessary trade barriers WTO

EPA has to consider costs of regulation in deciding what makes the risk “unreasonable”. In 1991 EPA’s ban on asbestos was struck down by a US court as the EPA was considered of not fully considered the costs of banning asbestos

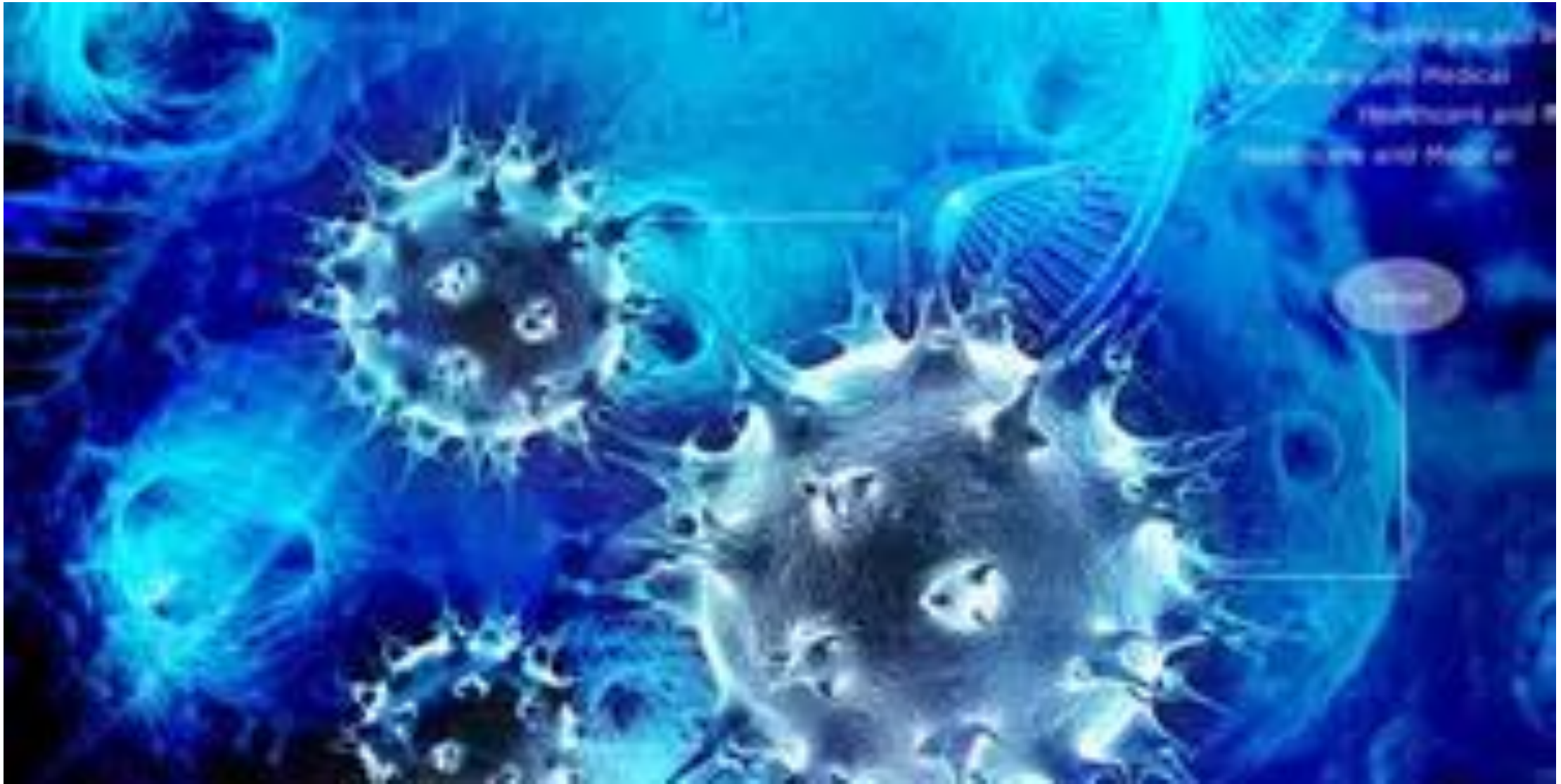
US TSCA Reform 2016

All Chemicals shall be reviewed on health and safety impact *without regard to cost or benefits:*

- Existing chemicals: eliminating the existing grand-fathering in of chemicals in use. If EPA after scientific evaluation concludes there is a "unreasonable risk", EPA shall issue a risk management rule which might require labelling or even ban the chemical. EPA can issue a Test Ruling (producer shall provide test on safety)
- New chemical: may not be produced before EPA review on level of risk (within 90-180 days). EPA can issue a Testing Ruling

NOTE: EPA (March 2015) agreed that nano-silver products intended to kill micro organisms qualify as pesticides and are in fact a new type of novel pesticide, the safety of which cannot be assumed on data pertaining to the macro-counterpart of a material (law suit was instigated in 2008 (!) by coalition of nonprofits led by the Center for Food Safety)

Concluding Remarks



Concluding Remarks

- Risks of emerging technologies tend to be inherently more uncertain, ill-defined and incomplete than more mature technologies
- US Regulatory assesses risks on a case-to-case basis, product-by-product basis and focusses on the product's application and its intended use, not on the technology itself. The EU is more restrictive to risks relating to scientific uncertainty on technology based on the " precautionary principle"
- General lack of transparency on nanomaterial risks (in particular "engineered" or "manufactured" nanomaterials) might flip the attitude of consumers / public from acceptance to fear and cause stigmatization of new nano technology developments (GMO Scenario)
- Innovation and market introductions of new nano products create facts and regulatory might be / is overtaken by events.
- The question is whether China's political ambitions to become a global leader in the field of new technologies might subordinate precaution to guide de adoption of nanotechnology to innovation.

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