

Documents concernant la mise au concours de l'étude «Nanomatériaux: répercussions sur l'environnement et la santé»

1. Description du sujet (en anglais)

⇒ pages 2-15

2. Aspects importants d'un point de vue «technology assessment» (en anglais)

⇒ pages 16-19

3. Données sur le teneur et le déroulement de l'étude

⇒ pages 20-21

4. Règles à suivre pour la présentation des dossiers de candidature

⇒ pages 22-23

Délai pour le dépôt des dossiers de candidature: 23. May 2011

1. Theme “Nanomaterials: impact on Environment and Health”: Overview

1.1. Nanotechnology research: new results on environmental and health risks

In the last decade there has been much speculation among scientists, risk sociologists, consumer and environmental bodies over possible positive and negative effects of synthetic nanomaterials on environment and health. On the positive side it is known that scientists are already developing products and innovations that could benefit the environment, especially in the field of solar energy. On the negative side it is believed that certain kinds of nanoparticles that are already used in more than 1000 products on the market¹ could potentially leak out, accumulate and damage the environment, for example impacting a variety of aquatic organisms, such as algae. And since environment and human species are connected via an intertwined relationship, there's no doubt among scientists that freely released nanomaterials could also impact our health, either directly through airborne particles or indirectly through the food chain. But knowledge on risks and benefits of nanomaterials has been so far off balanced: experts speak already about “benefits and potential benefits” while much of the debate concerning the risks has been characterized by the worlds “unknown” and “lack of knowledge”.

Unbalanced funding is to blame for the lack of solid data on environmental and health risks, according to a sharp 2007 Nature editorial: “*Few governments have put solid investment in the one type of research most consistently and urgently demanded [...]— on the health and environmental risks of technologies already embedded in hundreds of products on store shelves*” [1]. The journal was portraying the fact that on the one hand research on nanotechnology and its applications had been hugely funded worldwide: the US National Nanotechnology Initiative (NNI) has been awarded with more than \$ 13 billion in the decade 2000-2010 [2], while EU has allocated to nanotechnology related projects roughly \$ 7 billion within the Sixth (2002-2006) and Seventh Framework Program (2007-2013)². But on the other hand little effort was made to assess risks for the human beings and even less attention, if possible, was dedicated to the environmental impacts of nanomaterials, for example when they reach rivers and lakes.

However, in the last few years new funding distribution schemes have been put slowly into place. US NNI's research into the potential environmental, health, and safety (EHS) impacts of nanotechnology has risen to around \$ 92 million in 2010, a 5% of the annual total [2]; the EU provides similar relative figures for EHS research with respect to the total nanotechnology funding. Also the Swiss National Science Foundation (SNF) is committed to determine the dangers of nanomaterials, granting in 2009 ca. \$ 12.4 million (CHF 12 million) to the 5 years program NRP 64 – ‘Opportunities and Risks of Nanomaterials’. Goals of the program are: “*to provide data to develop tools to monitor the behaviour of nanomaterials and their potential impact on humans and the environment [...] to develop tools to maximize benefits and minimize human health and*

¹ www.nanotechproject.org/inventories/consumer/ - Inventory of nanotechnology-based consumer products currently on the market.

² http://cordis.europa.eu/nanotechnology/src/eu_funding.htm

environmental risks". In November 2010 the program has selected 17 projects that deal mainly with environmental and human health issues.³

Though the actual funding for EHS research is still valued too low by experts, researchers are producing new significant results on the environmental risks of synthetic nanoparticles (NPs) and more data are expected to come in the next future. Hence the discussion is now drifting on real studies and results, such as the ones regarding silver nanoparticles (Ag NPs) for example. Ag NPs are abundantly incorporated in textiles for their antibacterial activity, but could also slip off into waste water after multiple washing. If the released nanoparticles reach a certain amount, they could substantially reduce the activity of bacteria that are meant to treat water in the sewage purification plants, hence damaging the water purification process. Silver nanoparticles could even boost greenhouse gas emissions from the sludge, as Benjamin Colman and colleagues of the Duke University in Durham, North Carolina, US, recently found.⁴

On the other hand materials like carbon nanotubes are raising health concerns, since it has been shown that they could cause lung inflammation if inhaled.

These new results pose a new kind of problems, such how to cope with unexpected or unwanted drawbacks for environment and health without damaging a growing economy, that only in Switzerland has more than 600 companies and around 1300 employees.

1.2. Nano wonders that promise to benefit the environment

Products with embedded nanomaterials are entering the market in different sectors such as food industry, medicine, energy and environment. This trend has also been pictured in two interdisciplinary studies from TA-SWISS: 'Nanotechnology in medicine' [3] and 'Nanotechnology in the food sector' [4]. For example silver nanoparticles are used for their antibacterial activity in numerous consumer products such as textiles (Ag NPs in socks and shirts can kill the bacteria responsible for bad odours), cosmetics, PET bottles, laundry additives and even food supplements. Titanium dioxide (TiO₂) has been widely used in sunscreens since it reflects light away from the skin and increases protection, but TiO₂ added in nano form into sunscreens has recently become popular and cosmetically acceptable (this is because at smaller sizes it appears transparent when applied to the skin rather than leaving an opaque white cover). Nano-TiO₂ photo catalyst coatings have been applied to cars, boats, airplanes and facades to act as a antibacterial and self cleaning solution. Carbon nanotubes, long hollow cylinders made of carbon atoms that show both flexibility and strength, are used to make stiffer and lighter composite structures (e.g.: for bicycle frames, golf clubs, tennis rackets).

Some of these nano-based products could have a positive impact on the environment. As the 2009 TA-SWISS study 'Nanotechnology in the food sector' [4] showed, on the Swiss market there are

³ www.nfp64.ch/SiteCollectionDocuments/nfp64_bewilligte_projekte_d.pdf

⁴ www.sify.com/news/antibacterial-socks-could-raise-greenhouse-emissions-news-international-kiomkficdhb.html

several packaging products coated with nanomaterials to extend the shelf life of the foods: beer and fruit juices PET bottles are usually coated with a thin layer of amorphous carbon or silicon that acts as a barrier against gases (especially oxygen and carbon dioxide); plastic foils (especially PP but also PET, PA, PE, PVC and cellulose) for snacks, potato crisps, sweets and baked goods packages are covered with a layer of aluminium, aluminium oxide, or silicon oxide to improve the barrier features against oxygen, water vapor and aromatic substances. Food packaging is expected to have a positive impact on the environment, especially in the case of PET bottles. As reported in the TA-SWISS study *“the nano PET bottle creates about a third less greenhouse gas than the aluminium can, and as much as 60% less than the glass bottle [...] In Switzerland the complete substitution of these aluminium cans by nano PET bottles would lead to an annual relief of about 10 000 tons of CO₂ equivalents in terms of greenhouse potential”*. Unfortunately PET bottles with coated nanoparticles have also some drawbacks when it comes to disposal procedures, as discussed in chapter 1.3.

Other advantages for the environment could come by the so-called clean technology, a battery of eco-friendly applications and products with high energy efficiency [19]. Scientists are on the way to produce cheaper solar cells with higher degree of energy conversion than the current silicon solar cells, so in one technique nanowires are used to coat solar panels. Efforts are addressed to produce longer lasting batteries which require less recharging time, by engineering for example a nanostructure-design of electrode materials. Scientists also try to manufacture hydrogen powered fuel cells with catalytic nano-systems that aim to be cheaper and more efficient than the currently used platinum.

Water and wastewater treatment are other fields where nanotechnology shows some applications. Carbon nanotubes, nanoparticles, nanoporous membranes and dendrimers⁵ are contributing to the development of more efficient and cost-effective water filtration processes for water purification and desalination systems. Another emerging area of research is the development of novel nanomaterials with increased affinity, capacity, and selectivity for heavy metals and other contaminants in the process of water remediation.

Most recently nanomaterials have been introduced even in pesticide industry, promising better control and delivery of active ingredients, less environmental drift (unwanted dispersion of the sprayed pesticide) and perhaps better protection for agricultural workers [5].

Manufacturing bicycle frames, tennis rackets and tyres from carbon nanotubes, as well as coating PET bottles with silicon or making composite materials with embedded nanomaterials should allow less usage of material and energy than in conventional production. But the life-cycle environmental impacts and energy requirements of these new products are yet unknown. Scientists are trying to calculate them, weighting for example all the energetic costs from manufacturing to CO₂-related emissions, to disposal/recycling processes.

⁵ Dendrimers are three dimensional synthetic polymer molecules with a highly branched architecture, made of successive layers or 'generations' of branch units surrounding a central core

1.3. How nano impacts environment and health: real data, real worries

Some of the above applications could really benefit the environment, but there's a possibility that engineered nanoparticles, could eventually leak out in various ways, coming into contact with flora, fauna and human beings. *"Nanoparticles [A/N: coming from products or manufacturing procedures] can enter the environment through water, soil and air. And they can directly or indirectly affect human health, depending on factors like nanoparticles concentration"*, says Peter Gehr, director of the Swiss NRP 64 – 'Opportunities and Risks of Nanomaterials'.⁶

One of the main concerns is the possibility that nanoparticles enter into wastewater streams and wastewater treatment plants. In a 2008 paper Ralf Kaegi and colleagues from the Swiss Federal Institute of Aquatic Science and Technology (Eawag) showed that titanium dioxide (TiO₂) particles are detached in significant amounts *"from new and aged facade paints by natural weather conditions and are then transported by facade runoff and are discharged into natural, receiving waters"* [6]. According to Kaegi *"for an environmental risk assessment of NPs, both the exposure in the environment and the hazard, such as toxicity, needs to be taken into account"*. TiO₂ ecotoxicity is still debated but Carla Cherchi and April Gu from the Northeastern University, Boston, US, recently studied the impact of titanium dioxide exposure on cell growth, nitrogen fixation activity, and nitrogen storage dynamics in the blue-green alga *Anabaena variabilis* [7]. Cherchi stated in her article that TiO₂ *"potentially impacts important biogeochemical processes, such as carbon and nitrogen cycling"*.

Titanium dioxide can also enter directly the environment and come into contact with human beings during manufacturing processes. Airborne TiO₂ at high concentrations is a cause of concern in working environments. Recent studies in mice found that it may pose a potential risk of cancer and genetic disorders [8].

Similarly to TiO₂, silver nanoparticles (Ag NPs) can have significant interactions with algae, contributing to toxicity as a source of Ag⁺, according to Enrique Navarro of Eawag [9]. Ag NPs can be released from many products (as much as 259 in August 2009)⁷, for example from socks during laundry washing procedures, finding their way into waste water. Recent research performed by Benjamin Colman and colleagues analyses the impact of silver nanoparticles on a large sample of stream water, soil and sludge that was prepared with the aim of mimicking the real environment.⁸ They found a large drop in microbial activity within the sample (34%) and a level of released nitrous oxide (a greenhouse gas) that was four times higher than in the sample without Ag NPs. Some researchers think these results raise concerns on the potential impact that Ag NPs could have on both agriculture and climate change.

⁶ Personal communication

⁷ Kristin Schirmer: Ökotoxikologie, talk presentation, EMPA - www.empa.ch/plugin/template/empa/*/88877/---/l=1

⁸ www.sify.com/news/antibacterial-socks-could-raise-greenhouse-emissions-news-international-kiomkficdhh.html

Colman's results tackle another issue widely debated in nanotechnology risk assessment: the fact that to date the limited "lab scale" research may be misleading.⁹ *"The drop in its [A/N: in the large sample with Ag NPs] microbial activity is so large that it suggests the lab samples [A/N: usually smaller] are not a good guide to real-world behaviour,"* said Colman.⁷

But real field studies are currently a methodological problem: *"When dealing with natural systems, sizing techniques used for the characterization of the raw and pure particles (such as DLS and X-ray disc centrifugation) are not applicable due to the low particle concentration and or the polydispersity of natural systems, which makes the detection of NPs in the environment extremely challenging"*, said Kaegi [6]. Only recently Bojeong Kim and colleagues from Virginia Tech, Blacksburg, US, were able to get for the first time nanoparticle-level information of silver sulfide (Ag₂S) from a full-scale municipal wastewater treatment plant using analytical high-resolution transmission electron microscopy [10]. Kim highlighted that *"The type and source of silver that enter the wastewater plant can vary, but they are likely to form silver sulphide in the presence of reduced sulphur under anaerobic conditions in the plant"*.¹⁰ Bernd Nowack from the Swiss Federal Laboratories for Materials Science and Technology (EMPA) commented Kim's research stating that *"if the formation of silver sulfide nanoparticles from all forms of silver constitutes the standard case for wastewater treatment plants, the environmental risk assessment of silver and nanosilver would be simplified greatly [...] Silver bound to sulfur or organic ligands is many orders of magnitude less toxic than the free silver ion [...] It remains to be investigated, however, what the further fate of silver sulfide is in natural waters and whether it is transformed back to other silver forms"* [11].

Gehr emphasises the importance of knowing the transformation processes that occur during the life cycle of nanoparticles, because *"some nanoparticles can react with other substances in water, soil and air, substantially changing their properties and transforming themselves into products that can pose more or less environmental hazard than the original material"*.¹¹ Agglomeration and bio-accumulation processes of NPs have come under scrutiny by scientists, alongside with eco-toxicity and potential human toxicity of the aggregated forms.

Researchers agree that possible impacts on the food chain and long term toxic effects of NPs need to be considered. Rebecca Werlin and colleagues from the University of California recently found that cadmium selenide in nano-form can be transferred from prey to predator (in their case from bacteria to protozoa), and the material accumulates higher up in the food chain [12]. Similarly, a team of scientists from the University of Kentucky showed that gold nanoparticles accumulate in tobacco plants and then concentrate further in the caterpillars that eat them [13]. Hence the risk that NPs could indirectly bring negative effects to human health is not ruled out yet.

⁹ Mark R. Wiesner et al.: Decreasing Uncertainties in Assessing Environmental Exposure, Risk and Ecological Implications of Nanomaterials. *Environ. Sci. Technol.*, 43 (2009), 6458–6462. Cit.: *"While some classes of nanomaterials may be toxic in the lab and inert in natural environments, it is also possible that other classes of nanomaterials will become more lethal as a result of abiotic and biotic processing in complex ecosystems"*.

¹⁰ www.nanowerk.com/spotlight/spotid=18314.php

¹¹ Personal communication

Kaegi points also out that “*unknown are the long-term, evolutionary effects on living organisms of the exposure to new types or concentrations of NPs*” [6]. As Gehr explains “*current scientific data deal only with short exposure times and acute health effects, while long-term impacts on health are not being investigated*”.¹²

Emission in the air during manufacturing or after detachment from surfaces and composite structures are other possible ways through which NPs can enter the environment, as already explained for TiO₂. This is especially true for nanotubes, which are safe when bound to other materials (e.g.: in a bicycle frame), but become a big cause of concern for human and mammal health in general if they are freely released, for example during the production phase, because they can be easily inhaled. Kenneth Donaldson and colleagues from the University of Edinburgh, UK, showed in a 2008 Nature Nanotechnology paper that inhaling long and thin nanotubes may result in asbestos-like health effects (such as mesothelioma cancer) [14]. Their findings caused alarm in the scientific community but Donaldson found a positive angle in them: “*Short or curly carbon nanotubes did not behave like asbestos, and by knowing the possible dangers of long, thin carbon nanotubes, we can work to control them*”.¹³ In a November 2010 Nature Biotechnology paper John Frangioni and colleagues of the Beth Israel Deaconess Medical Center, Boston, US, tracked how nanoparticles instilled into rats’ lungs travel through the body, depending on the NPs chemical composition, size and surface charge [15]. Frangioni showed that non-positively charged particles smaller than 34 nanometres in diameter are rapidly transported from lungs to lymph nodes, and that nanoparticles smaller than six nanometres with equal positive and negative charge are quickly cleared from the body via the kidneys.

Synthetic nanomaterials could eventually come into contact with soil, water and air after or through waste-treatment processes. Currently there is no practical way to recycle nanomaterials embedded in products, hence such products are treated like normal ones. Besides it remains challenging how to dispose of nano-products. Pure nanomaterials like Ag NPs are easily treated and also the thin layer of silicon coating in PET bottles can be processed in alkaline solutions, but it’s not possible to separate the nanoparticles incorporated within the bottle.¹⁴ Many new methods are being tested, but they are at an experimental stage. With respect to the disposal of nanotubes we have no option at the moment, since burning them could cause dispersion through the exhaust air.

Disposal of nanomaterials resulting from manufacturing procedures it’s another major issue, as reported in a 2010 Nature Nanotechnology commentary “*A survey of Swiss companies handling nanoparticles showed that a number of different nanosize materials were already being used in quantities exceeding 1 ton/yr per company [...] About 85% of researchers declared disposing of nanomaterials either without a special procedure (24.3%) or with the same procedure as for other chemicals (61.0%)*” [23].

¹² Personal communication

¹³ www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.item&news_id=432977

¹⁴ Carsten Eichert: ‘Nanomaterialien - Herausforderungen für die Recyclingindustrie’, talk, IFAT ENTSORGA 2010 - www.quarec.de/cmsMedia/Downloads/Pressematerial/Nano_Vortrag_IFAT_2010_0.pdf

1.4. Ethical debate on nanomaterials

The ethical debate in nanotechnology context is a quite new but important field, even though is being often underestimated with respect to more noisy debates such as the ones on regulation (see chapter 1.5.) and social acceptance (see chapter 1.6.). In the last few years many ethically relevant issues have been identified for nanotechnology: among them risk management related to nanoparticles, equity and distributive justice (of opportunities and risks), sustainability, privacy, military use, nanomedicine, artificial life and human enhancement [24]. Experts agree that these ethical issues and the related questions seem not new compared to the ethical analysis applied to other technologies, nonetheless new and ethically interesting cases could arise from nanotechnology.

The risk debate on nanoparticles is recognized to be a predominant ethical aspect. Armin Grunwald from the Karlsruher Institut für Technologie (KIT), Germany, states that ethical analysis should serve as orientation process ex-ante “*to shed light on the normative premises of the options at hand as well as on the criteria of decision-making*” [25]. Grunwald has made a comprehensive analysis of the risk management related to the use and spread of nanoparticles [24, 25]. There he finds “*that given the current lack of knowledge and uncertainty of the risks posed by nanoparticles [...] classical risk assessment is not applicable*”.¹⁵ Instead, “*according to the state of the art in toxicological research on nanoparticles, there is a reasonable concern of the possibility of hazards*”, which allows for the precautionary principle to be applied. The application of the precautionary principle in the field of nanoparticles is not disputed.

What is discussed, and not only by ethicists (e.g.: see calls for moratorium in chapter 1.6.), is what measures should follow from the application of the precautionary principle. Grunwald shares the position of many [26] for a weak interpretation of the precautionary principle: “*the mere possibility of serious harm implied by a wider use of nano-particles does not legitimate to use the precautionary principle as argument for a moratorium or other prohibitive measures*” [25]. Translating this into risk regulation, it means that “*no really new regulatory measures are needed [...] and [...] treating nanoparticles as new chemicals seems to be the adequate risk management approach*” [ibid.].

Swiss ethicist Andreas Bachmann differs on some arguments with Grunwald. In fact Bachmann agreed with US Environmental Protection Agency (EPA) that in 2006 wanted to apply the strong precautionary principle with respect to the manufacturing of products with unbound nanosilver.^{16,17} Bachmann said that “*if there are reasonable grounds for thinking that, under particular conditions, synthetic nanoparticles can severely harm humans and the environment, then it is justified to*

¹⁵ In quantitative risk assessment, risk is the product of the quantitative measures of the probability of damage and of the extent of possible hazards

¹⁶ EPA statements: www.washingtonpost.com/wp-dyn/content/article/2006/11/22/AR2006112201979.html

¹⁷ Despite the 2006 statements, in the 2007 final federal register notice EPA decided not to regulate products containing nanosilver: www.nanolawreport.com/2007/09/articles/epa-finally-issues-nanosilver-notice/

*reverse the burden of proof*¹⁸ and require manufacturers to prove that the (free) nanoparticles used in their products are harmless”.¹⁹

Beyond these divergences, there is no doubt that future knowledge could change everything. For Grunwald it is important to “*establish comprehensive evaluation of the state of knowledge and its evaluation with respect to implications for risk management*” [25].

Another important ethical aspect connected with nanomaterials and environment is distributive justice. Bachmann analyses this issue in terms of intragenerational and intergenerational justice. The former concerns the so-called nano-divide, the unequal distribution of and access to nanotechnological knowledge and products between developed and developing countries. In this respect Bachmann makes the example of nanobased water filtration systems: starting from the assumption that “*drinking water is a basic need [...], if nanobased water filtration systems can help meet this need they must be provided to those who need them. Inaccessibility due to unaffordability would be unjust*”.²⁰ Intergenerational justice or sustainability “*is about the expected positive as well as possible negative effects of nano(bio) technology on the livelihood of future generations*” [27]. Nanotechnology, and also the use of nanomaterials, has raised great expectations with respect to sustainability, claiming lower energy and material consumption, and lower waste and pollution production. Central to this aspect would be life-cycle analyses of the nanoparticles.

1.5. Current regulations for nanomaterials

To date no country in the world has adopted a specific legislative framework on nanomaterials; the main approach so far has been to include them within the regulations already in place.

The European Community has stated that environmental regulation for nanomaterials “*relates in particular to integrated pollution prevention and control (IPPC directive), the control of major accident hazards involving dangerous substances (Seveso II directive), the water framework directive and a number of waste directives*”[16]. None of these directives explicitly addresses the risks of nanomaterials. According to the EU “*nanomaterials are covered by the “substance” definition in REACH.*” The law REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances, in force since 2007) gives manufacturers and importers the responsibility to submit a registration dossier for substances that they manufacture or import at or above one ton per year. But as stated by Georg Karlaganis “*under REACH there are no provisions referring*

¹⁸ Reversal of burden of proof is a point in the strong interpretation of the principle: it is not the State, but the proponent (producer) of a hazardous technology who must prove that it is harmless (for example, drugs or food additives).

¹⁹ www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/gutachten/e-Gutachten-Synthetische-Nanopartikel-2007.pdf

²⁰ Sixth Session of the Intergovernmental Forum on Chemical Safety, Dakar, 2008 - www.who.int/ifcs/documents/forums/forum6/ppt_nano_bachmann.pdf

specifically to nanomaterials, and substances at the nanoscale are currently regarded as not being different to the bulk form”. ²¹

In March 2009 the EU adopted a new legislation on cosmetics with nanomaterials, requiring by 2012 the labelling, definition and safety assessment of the products.²² In 2011 the EU will conduct a new regulatory review of nanomaterials, but ahead of that the Belgian EU presidency has in September 2010 proposed to create a specific nanomaterial register under REACH and mandatory labelling for all consumer products.²³

Also in US many nanoscale materials are regarded as normal "chemical substances" under the current law, specifically the Toxic Substances Control Act (TSCA). The FDA did not suggest so far the need for any immediate nano-specific regulatory action. The Environmental Protection Agency (EPA) issued the first specific rules on engineered nanomaterials on September 17, 2010, when it published Significant New Use Rules (SNURs) for carbon nanotubes, which, among other things, ban releases of nanotubes into water *“to prevent any potential unreasonable risks”*.²⁴ The US National Institute for Occupational Safety and Health (NIOHS) has published in November 2010 a draft Intelligence Bulletin on ‘Occupational Exposure to Carbon Nanotubes and Nanofibers’ where it suggests a recommended exposure limit (REL) of 7 µg /m³ of respirable carbon nanotubes in workplaces.²⁵

In Switzerland synthetic nanomaterials do not receive special treatment under current legislation, but the country has committed to inform the population and to introduce labelling of nano-containing cosmetics, and eventually food, in coordination with the EU.²⁶ In December 2008 the Swiss Federal Office of Public Health (FOPH) and the Swiss Federal Office for the Environment (FOEN) launched the precautionary matrix (A/N: called Vorsorgeraster) for synthetic nanomaterials,²⁷ as part of the Swiss Action Plan ‘Synthetic Nanomaterials’, issued in April 2008. Trade and industry businesses can voluntarily fill up the precautionary matrix, a scheme that classifies the substances based on their harmfulness and application, including an evaluation of the probability and the extent of exposure of people and environment to the nanoparticles. The matrix does not provide risk assessment.

On 17 December 2010 the Swiss State Secretariat for Economic Affairs SECO elaborated a safety data sheet (SDS) with guidelines and information on safety procedures for synthetic nanomaterials, aimed at professionals and commercial users. In December 2010 SUVA, the Swiss National

²¹ Georg Karlaganis: ‘Nanotechnologies: Governance Models’, talk, UNITAR Nano Workshop 2009 - www2.unitar.org/cwm/publications/event/Nano/Lodz_11_Dec_09/documents/B_Nano_Ka_Governance.pdf

²² www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+IM-PRESS+20090323IPR52331+0+DOC+XML+V0//EN

²³ www.euractiv.com/en/food/reach-register-ensure-traceability-nanomaterials-news-497781

²⁴ www.nanolawreport.com/uploads/file/75%20FR%2056880.pdf

²⁵ www.cdc.gov/niosh/docket/review/docket161A/pdfs/carbonNanotubeCIB_PublicReviewOfDraft.pdf

²⁶ www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch_id=20094170

²⁷ www.bag.admin.ch/themen/chemikalien/00228/00510/05626/index.html

Accident Insurance Fund, published its annual report on occupational exposure limit: 'Grenzwerte am Arbeitsplatz 2011, MAK-Werte, BAT-Werte, Grenzwerte für physikalische Einwirkungen'.²⁸ In the report SUVA established exposure limits for titanium dioxide nanoparticles (0.1mg/m³) and for carbon nanotubes (0.01 fibers/ml).

At intergovernmental level there have been sparse initiatives, ranging from recommendations, to codes of conduct, and draft regulations. In 2008 the Intergovernmental Forum on Chemical Safety released the 'Dakar Statement on Manufactured Nanomaterials'²⁹ and in 2009 the EU commission released a 'Code of conduct for responsible nanosciences and nanotechnologies research'.³⁰ Both contain general recommendations and call for activities conducted in accordance with the precautionary principle.

Despite these efforts, institutions like the British insurance market Lloyd's are complaining on the lack of specific regulation governing the use of nanotechnology. Lloyd's called the current situation "regulatory abyss" in a recent article: *"the lack of understanding of the risks around nanotechnology has led to a regulatory gap with 'nanospecific' regulation still lacking in most countries"*, with Federal and State authorities in the US that are *"behind Europe in coordinating their moves to regulate the use of nanomaterials"*.³¹ The insurance industry says it's ready to initiate steps to *"cope with the continuing uncertainty around nanotechnology"*, and suggests some mitigation strategies such as *"consider the whole life cycle of carbon nanotubes and their impacts on traditional lines of business"*.

1.6. Nano-dialogue for the masses: does missing info and regulation lead to fear?

According to the last Eurobarometer, current attitudes towards nanotechnology are generally positive, with six out of ten EU citizens supporting it [17]. But optimism over the possible positive effects of the technology is slightly declining since 2002 and safety emerges as a dividing issue among supporters and opponents. With the exception of France (see p.13), there are no news of the uncontrolled fear that characterized the GM crisis, which led to the public rejection of the technology. But given the current situation in nanotechnology risk assessment and in the regulatory field there should be no surprise that NGOs, environmental groups and active citizens are calling for more clarity.

Consumers' organizations are asking for more regulation. It's the case of the Swiss Stiftung für Konsumentenschutz (SKS), which in a 2010 press release asked the Swiss Federal Council for more urgency in considering the need of new regulations: *"Der Bundesrat wird nun den gesetzgeberischen Handlungsbedarf überprüfen lassen. Allerdings ist es kaum verständlich, weshalb sich*

²⁸ www.sapros.ch/images/supplier/220/pdf/01903_d.pdf

²⁹ www.who.int/ifcs/documents/forums/forum6/report/en/index.html

³⁰ http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf

³¹ www.lloyds.com/News-and-Insight/News-and-Features/360-News/Emerging-Risk-360/Regulators-get-to-grips-with-nanotechnology

*die Behörden mit der überprüfen Zeit lassen bis 2011. Die Umsetzung wird nochmals Jahre in Anspruch nehmen, während die Forschung und Entwicklung von Produkten mit synthetischen Nanopartikeln unaufhaltsam voranschreiten”.*³²

The organisation Schweizerische Arbeitsgruppe Gentechnologie (SAG) has a long history of campaigning against genetic engineering and recently it has started following the developments in nanotechnology. With the aim of protecting human health and the environment against all possible negative effects of NPs, SAG asks for more regulation and for clear labelling of nano-products.³³

The safety issue of NPs has also entered the Swiss Parliament: in October 2010 Graf Maya, a centre-left Green parliamentarian, made an interpellation in the Chamber, asking, among other things, if it's the case to ban nano-products until new regulations come into force.³⁴

Similar calls are not new: in a 2008 report the environmental organization Friends of the Earth (FOE) called for a moratorium of the nano-products in food and agriculture until their potential consequences for health and environment are made clear.³⁵ In November 2010 FOE released another report where it states that nanotechnology fails to exhibit much potential as a solution to global warming, resource depletion or pollution, instead its applications come at a large environmental costs (e.g.: manufacturing of nano-products requires large amounts of energy).³⁶

Current manufacturing procedures in nanotechnology imply passively encapsulating nanoparticles in different systems, while active nano-devices or nanorobots remain at a speculative or draft level. Nonetheless, the Canadian ETC group is actively campaigning against similar risks and calling for a moratorium on nanoparticles since 2003: *“nanotechnology [...] involves atomic manipulation and will make possible the fusing of the biological world and the mechanical [...] the ETC Group believes that a moratorium should be placed on research involving molecular self-assembly and self-replication”.*³⁷

To cope with the fear that nanotechnology could lose public support, or even become the 'new GM' or the 'new asbestos', scientists, citizens, policy makers and various institutions (e.g.: EU, OECD, technology assessment centres) have put into action studies, initiatives, dialogue and communication procedures on nanotechnology from the very beginning of the decade. Most of them deal with nanotechnology at a general level, without taking into account a specific theme, such as the environment.

³² <http://konsumentenschutz.ch/medienmitteilungen/archive/2010/03/09/klare-regeln-fuer-die-nanotechnologie-notwendig.html>

³³ www.gentechnologie.ch/cms/index.php?option=com_content&view=article&id=153&Itemid=96

³⁴ www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch_id=20103825

³⁵ Out of the laboratory and on to our plates, Friends of the Earth report, p.46 (March 2008) - www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf

³⁶ www.foe.org/nanotechnologys-true-climate-cost-exposed

³⁷ www.etcgroup.org/en/issues/nanotechnology

In UK the Royal society published the report ‘Nanoscience and nanotechnologies: opportunities and uncertainties’ (2004).³⁸ In Denmark the survey ‘Citizen’s attitudes towards nanotechnology’ was performed in 2004.³⁹ The UK Safenano Initiative led the EMERGNANO project, a global review of active research into the environment, health and safety risks of nanotechnology (concluded in 2009).⁴⁰ Similarly the NanoTrust project of the Institute of Technology Assessment of the Austrian Academy of Sciences collects since 2007 information on possible health and environmental risks and on societal aspects of nanotechnologies.⁴¹

France has been very active with outreach initiatives. The French Commission of Public Debates organized the ‘débât public Nanotechnologies’ in various French cities in late 2009 and early 2010. Unfortunately the initiative was strongly opposed by a small group of environmentalists that disputed the legitimacy of the public discussions. They labelled the events as one-sided and a whitewash, they rallied against the debates and eventually succeeded in shutting down many of them with slogans such as “*Nano, it's not green, it's totalitarian*”.⁴²

Dialogue procedures are ongoing at the EU level, for example within the FP7 project FRAMING-NANO (2009-2013), which involves the development of a workable governance plan for nanotechnologies.⁴³ A more informal experience of governance platform is the ‘Behördendialog’, which encompasses representatives of German-speaking authorities, organized by The Innovation Society, St. Gallen.

TA-SWISS has played his role in the field, assessing chances and challenges of nanotechnology within clearly-defined subjects. Besides the two interdisciplinary studies [3, 4] already cited, in 2006 TA-SWISS published the publifocus ‘Nanotechnologies – meaning for health and environment’ [18]. The latter gives a glimpse of how lay people, in absence of specific data, try to define the unknown: “*They compared the possible negative effects of nanotechnologies to the dangers of asbestos or ultrafine dusts and illustrated potential benefits taking examples from information and computer technology*”. The publifocus’ participants also brought up concerns about the environment, specifically about nano-products disposal: “*I asked myself, how can you protect yourself if the particles can’t be filtered at all? In large production, there is the question of release of the particles, during disposal, too. After all, there are disposal sites that today themselves have to be disposed of*”, said a participant.

³⁸ www.nanotec.org.uk/finalReport.htm

³⁹ www.tekno.dk/subpage.php3?article=1093&toppic=kategori11&language=uk

⁴⁰ www.safenano.org/Emergnano.aspx

⁴¹ <http://nanotrust.ac.at/nano.ita.en/index.html>

⁴² www.nano.org.uk/news/367/

⁴³ www.framingnano.eu/

1.7. Literature

- [1] Enough talk already. Nature Editorial, Vol. 448, p. 1-2 (5 July 2007)
- [2] Corie Lok: Small Wonders. Nature news feature, Vol. 467, p.18-21 (02 September 2010)
- [3] Walter Baumgartner et al.: [Nanotechnologie in der Medizin](#). Studie des Zentrums für Technologiefolgen-Abschätzung (TA-SWISS), TA-47/2003, Bern, (2003)
- [4] Martin Möller et al.: [Nanotechnologie im Bereich der Lebensmittel](#). Editor: TA-SWISS. Zurich: vdf Hochschulverlag AG, ETH Zürich (2009)
- [5] D. Stone et al.: Exposure Assessment: Recommendations for Nanotechnology-Based Pesticides. Journal of Occupational and Environmental Health, 16 (2010), No 4
- [6] R. Kaegi et al.: Synthetic TiO₂ nanoparticles emission from exterior facades into the aquatic environment. Environmental Pollution, 156 (2008), 233-239
- [7] C. Cherchi and A. Z. Gu: Impact of Titanium Dioxide Nanomaterials on Nitrogen Fixation Rate and Intracellular Nitrogen Storage in *Anabaena variabilis*. Environ. Sci. Technol., 44 (2010), 8302–8307
- [8] B. Trouiller et al.: Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability in vivo in Mice. Cancer Res, 69 (2009), 8784-8789
- [9] E. Navarro et al.: Toxicity of Silver Nanoparticles to *Chlamydomonas reinhardtii*. Environ. Sci. Technol., 42 (2008), 8959–8964
- [10] B. Kim et al.: Discovery and Characterization of Silver Sulfide Nanoparticles in Final Sewage Sludge Products. Environ. Sci. Technol., 44 (2010), 7509–7514
- [11] Bernd Nowack: Nanosilver Revisited Downstream. Science, 330 (2010), 1054
- [12] R. Werlin et al.: Biomagnification of cadmium selenide quantum dots in a simple experimental microbial food chain. Nature Nanotechnology, Advance Online Publication (19 December 2010)
- [13] Jonathan D. Judy et al.: Evidence for Biomagnification of Gold Nanoparticles within a Terrestrial Food Chain. Environ. Sci. Technol., Web Article ASAP (3 December 2010)
- [14] C. A. Poland et al.: Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. Nature Nanotechnology 3(2008), 423 - 428
- [15] H. S. Choi et al.: Rapid translocation of nanoparticles from the lung airspaces to the body. Nature Biotechnology Letter (Published online on 07 November 2010)
- [16] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - Regulatory aspects of nanomaterials [SEC(2008) 2036]
- [17] Eurobarometer ‘Europeans and Biotechnology in 2010, Winds of change?’ - European Commission report (October 2010)
- [18] TA-SWISS publifocus: [‘Nanotechnologies – meaning for health and environment’](#) (2006)

- [19] BAFU Magazin 'umwelt' 3/2010: Nanotechnologie (26.08.2010)
- [20] Challenging Futures of Science in Society - The MASIS report, European Commission Directorate-General for Research, pp. 80 (2009)
- [21] Thomas Mueller: Nanotechnologie: Die naechste Kandidatin fuer ein Moratorium. Basler Zeitung, (15 July 2003)
- [22] D. Kühnel et al.: Agglomeration of tungsten carbide nanoparticles in exposure medium does not prevent uptake and toxicity toward a rainbow trout gill cell line. *Aquatic Toxicology*, 93 (2009), 91-99
- [23] F. Balas et al.: Reported nanosafety practices in research laboratories worldwide. *Nature Nanotechnology commentary*, 5 (2010), 93-96
- [24] A. Grunwald: Ethics of nanotechnology. State of art and challenges ahead. In: Schmid, G. (Editor): *Nanotechnology*. Weinheim: WILEY-VCH (2008), 245-287
- [25] A. Grunwald: Nanoparticles: Risk management and the precautionary principle. In: Jotterand, F. (Editor): *Emerging conceptual, ethical and policy issues in bionanotechnology*. Berlin: Springer (2008), 85-102
- [26] R. Haum et al.: *Nanotechnology and Regulation within the Framework of the Precautionary Principle. Final Report for ITRE Committee of the European Parliament*". Berlin: Schriftenreihe des IÖW (Institut für ökologische Wirtschaftsforschung) 173/04 (2004).
- [27] A. Bachmann: *Nanobiotechnologie. Eine ethische Auslegeordnung*. Editor: ECNH. Bern: Verlag BBL (Bundesamt für Bauten und Logistik, 2006).

1.8. Weblinks

- SNF Program NRP 64 - Opportunities and Risks of Nanomaterials: www.nfp64.ch
- BAG on nanotechnology: www.bag.admin.ch/themen/chemikalien/00228/00510/index.html?lang=de
- BAFU on nanotechnology: www.bafu.admin.ch/chemikalien/01389/01393/index.html?lang=de
- US EPA on nanotechnology: www.epa.gov/ncerqa/nano/
- US National Nanotechnology Initiative (NNI): <http://nano.gov>
- Nanotechnology homepage of the European Commission: <http://cordis.europa.eu/nanotechnology/>
- REACH: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
- Schweizerische Arbeitsgruppe Gentechnologie (SAG): www.gentechnologie.ch/cms/
- ETC group on nanotechnology: www.etcgroup.org/en/issues/nanotechnology
- Friends of the Earth on nanotechnology: www.foe.org/healthy-people/no-nano-food-and-agriculture

2. Aims of a new TA-SWISS study and relevant questions

As we have seen in the above paragraphs and also Ulrich Fiedeler from the Austrian Institute of Technology Assessment confirmed to us *“there is no comprehensive study on possible adverse effects of nanotechnology on the environment [...] eco-toxicological risks are not discussed separately but often together with risks of human toxicological and only for a specific nanomaterial”*.⁴⁴ But upcoming new results in the field (possibly also from the Swiss program NRP 64 – ‘Opportunities and Risks of Nanomaterials’), a set of rules that is slowly changing and some alarming public reactions (e.g.: France) make TA-SWISS believe that the potential effects of nanomaterials on the environment constitute an emerging and challenging theme, which should be analysed in a specific new TA study. Such a study would have the following aims:

- to give an overview over present/future products and applications containing nanomaterials that may benefit or damage the environment
- to collect and review the ongoing research on nanomaterials that could impact health and environment
- to determine which nanomaterials are relevant for health and environment, and among them which ones can easily reach the exposure levels that could affect humans and flora/fauna (it is important to highlight the connection between environment and health)
- to address specific critical issues such as waste water treatment, disposal, recycling and long term health/environmental effects
- to discuss the methodological approaches that could be useful in analyzing long term effects of nanomaterials
- to determine which nanomaterials have the potential to propagate in the future thanks to the diffusion of the products containing them, and what possible risks do they carry along
- to analyze the current risk debate on nanoparticles and to identify the relative ethical questions and the current risk management strategies
- to give an overview of the current regulations at the EU and Swiss level, specifically concerning nanomaterials and environment, highlighting their positive/negative aspects
- to formulate recommendations for further regulatory developments and to weight such recommendations with respect to the economic potential of nanotechnology

⁴⁴ Personal communication

2.1. Relevant Questions for a new TA-SWISS study

In the previous chapters we highlighted some issues regarding nanomaterials' impact on the environment. With respect to those issues the following questions may be of interest for a TA-SWISS study (questions are in bold, preceded by a short introduction taken from the overview):

- a) Some of these nano-based products could have a positive impact on the environment [...] As reported in the TA-SWISS study *“the nano PET bottle creates about a third less greenhouse gas than the aluminium can, and as much as 60% less than the glass bottle [see p. 3-4]*

What products/applications containing nanomaterials could benefit the environment? Which ones do have the best potential of success? Can we determine the life-cycle environmental impacts and energy requirements related to their usage (in other words are they sustainable)?

- b) *“Nanoparticles [A/N: coming from products or manufacturing procedures] can enter the environment through water, soil and air. And they can directly or indirectly affect human health, depending on factors like nanoparticles concentration”*, says Peter Gehr [...] In a 2008 paper Ralf Kaegi and colleagues from the Swiss Federal Institute of Aquatic Science and Technology (Eawag) showed that titanium dioxide particles are detached in significant amounts *“from new and aged facade paints [...] [see p. 5]*

Which nanomaterials could easily get into contact with environment and human beings through water, soil and air? Which ones are relevant for environment and health? Can we assess with certainty their exposure, eco-toxicity and toxicity?

- c) Products with embedded nanomaterials are entering the market in different sectors such as food industry, medicine, energy and environment.. [see p. 3]

Which nanomaterials have more potential to diffuse in the future, due to big market shares of the relative products? What possible risks do they carry along?

- d) Currently there is no practical way to recycle nanomaterials embedded in products, hence such products are treated like normal ones. Besides it remains challenging how to dispose of nano-products. Pure nanomaterials like Ag NPs are easily treated and also the thin layer of silicon coating in PET bottles can be processed in alkaline solutions, but it's not possible to separate the nanoparticles incorporated within the bottle. [see p. 7]

What happens to the incorporated nanoparticles with the current disposal procedures? Which are the possible consequences of recycling products containing nanomaterials like normal products? Do we have alternative materials to replace the rare ones?

- e) Gehr emphasises the importance of knowing the transformation processes that occur during the life cycle of nanoparticles [...] As Gehr explains *“current scientific data deal only with short exposure times and acute health effects, while long-term impacts on health are not being investigated”*. [see p. 6-7]

What do we know about the potential transformation processes of synthetic nanomaterials? What are the possible long term toxic effects of nanomaterials on flora, fauna, agriculture and human health? What kind of studies/approach do we need in order to analyze the long term effects of NMs? Can we zip the research time to obtain correct results about future effects and put the right counter-strategies into place? Is there a specific health related risk for airborne nanotubes?

- f) Only recently Bojeong Kim and colleagues from Virginia Tech, Blacksburg, US, were able to get for the first time nanoparticle-level information of silver sulfide (Ag₂S) from a full-scale municipal wastewater treatment plant using analytical high-resolution transmission electron microscopy. [see p. 6]

Are the results of B. Kim and colleagues indicating that characterization and detection of nanomaterials in real-field studies are becoming easier?

- g) In the last few years many ethically relevant issues have been identified for nanotechnology: among them risk management related to nanoparticles, equity and distributive justice (of opportunities and risks), sustainability, privacy, military use, nanomedicine, artificial life and human enhancement [24]. Experts agree that these ethical issues and the related questions seem not new compared to the ethical analysis applied to other technologies, nonetheless new and ethically interesting cases could arise from nanotechnology. [see p. 8]

What are the major ethical aspects involved with nanomaterials and the environment? Are some of them specific for nanotechnology and novel to ethics? Are there relations to recent or ongoing ethical debates in other technology fields?

- h) The risk debate on nanoparticles is recognized to be a predominant ethical aspect. Armin Grunwald from the Karlsruher Institut für Technologie (KIT), Germany, states that ethical analysis should serve as orientation process ex-ante “*to shed light on the normative premises of the options at hand as well as on the criteria of decision-making*”[25]. [see p. 8]

What is the current status of the ethical debate on risks due to nanoparticles? Is the precautionary principle still the right approach or do we need further/different ethical instrumentation? What implications should follow from it with respect to risk management (e.g.: moratorium, weak/hard application of the precautionary principle, ...)? Can society cope with simple means such as approval/moratorium in a complicated domain like the one here discussed?

- i) But given the current situation in nanotechnology risk assessment and in the regulatory field there should be no surprise that NGOs, environmental groups and active citizens are calling for more clarity. [see p. 11]

Who are the stakeholders and what’s their role in the discourse about nanomaterials and environment? Is there a potential risk of public rejection of the field?

- j) To date no country in the world has adopted a specific legislative framework on nanotechnology. The main approach so far has been to include nanomaterials within the regulations already in place [...] In Switzerland [...] trade and industry businesses can voluntarily fill up the precautionary matrix, a scheme that classifies the substances based on their harmfulness and application. [see p. 9-10]

Should we continue implementing nano in the EU law REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) and other regulations already into place or should we build a complete new regulation framework? And how do we deal with nanomaterials that are already present on the market?

3. Données sur le teneur et le déroulement de l'étude

3.1. Contenu de l'étude

Cette **étude interdisciplinaire** doit évaluer **les chances et les risques que pourraient représenter les nouveaux nanomatériaux pour l'environnement et la santé**. Le but principal de cette étude est d'identifier les **nanomatériaux qui pourraient interagir avec la santé et l'environnement**, puis de déterminer lesquels peuvent atteindre un taux de dissémination qui pourrait affecter la faune, la flore et les êtres humains. Pour ce faire, il est essentiel d'examiner en détails **les recherches actuellement en cours** sur l'effet qu'ont les nanomatériaux sur l'environnement et la santé, ainsi que sur leur sécurité. Cette étude devra également **déterminer quels sont les produits répandus sur le marché** qui contiennent des nanomatériaux. Les principaux enjeux sont le traitement des eaux usées, l'élimination et le recyclage des déchets et les effets à long terme des nanoparticules sur la santé et l'environnement.

Centrées sur le nombre croissant de produits contenant des nanomatériaux qui sont mis sur le marché, les recherches doivent permettre **d'évaluer l'évolution des tendances du marché actuelles et à venir**. L'élaboration de scénarios doit permettre d'ébaucher quelle importance aura dans le futur la diffusion des nanomatériaux et quelles implications économiques en dépendent, en particulier pour la Suisse.

Il est important que cette étude analyse l'actuel débat éthique autour des risques relatifs aux nanoparticules. Elle doit également déterminer les questions éthiques que ce débat sous-tend et qui sont nécessaires pour définir **les conditions d'acceptation et de gestions de ces risques**. Cette étude doit en outre évaluer **l'acceptation de cette technologie par le public** et les attentes des différents groupes d'intérêts. Il est également important d'aborder les problèmes inhérents à la manière de communiquer aujourd'hui sur les risques. Enfin, cette étude doit examiner la réglementation actuelle et ses tendances au niveau national et international.

Sur la base des résultats de ces recherches, l'étude doit **proposer une liste de recommandations**, adressée aux organes de régulation et aux décideurs politiques, plus particulièrement en Suisse.

3.2. Dépôt des dossiers

Les propositions doivent satisfaire aux «Règles à suivre pour la présentation des dossiers de candidature» selon le point 4 de ce document (page 22). Les offres doivent être adressées à l'adresse électronique ci-dessous (données pdf). **La date limite de soumission est fixée au 23 mai 2011**. La décision concernant le choix d'une des propositions devrait être connue en juin 2010.

3.3. Réalisation de l'étude

Le Secrétariat du Centre d'évaluation des choix technologiques mettra sur pied un groupe de spécialistes (dit groupe d'accompagnement) représentatif des différents aspects thématiques de l'étude. La proposition acceptée sera présentée à ce groupe d'accompagnement avant que ne débute sa réalisation, lequel pourra, d'entente avec le Secrétariat, influencer sur les priorités et la marche à suivre. Pendant la durée de l'étude, le groupe de projet rédigera de trois à cinq documents de travail ou rapports intermédiaires à l'intention du groupe d'accompagnement et du Secrétariat. Ces comptes rendus serviront de base de discussion, étant entendu que chaque nouvelle phase du projet ne sera entreprise qu'après accord avec ces deux instances.

3.4. Budget et calendrier

Budget maximum: 120'000.- CHF

Début de la réalisation: juillet 2011 (ou selon accord)

Durée du projet: 12-15 mois

4. Règles à suivre pour la présentation des dossiers de candidature

Nous vous prions de structurer votre proposition selon le schéma de soumission suivant (étant entendu que les sous-rubriques ne sont que des **exemples** et peuvent, par conséquent, être adaptées à la spécificité du cas):

1. Analyse de la situation: positionnement et justification de la recherche

- Raisons justifiant une étude TA sur le thème proposé
- Portée nationale et internationale du sujet
- Enjeux technologiques, économiques, politiques et sociaux
- État des connaissances avec mise en relief des aspects utiles à la TA
- Avancées prévisibles dans le domaine d'investigation envisagé

2. Exposé de la problématique

- Questions auxquelles il s'agit de répondre
- Objectifs concrets de la proposition ou de l'étude
- Nouveaux résultats et nouvelles conceptions amenés par l'étude

3. Structuration et délimitation de la recherche

- Groupes ciblés et points de focalisation
- Eventuellement: subdivision en projet principal et sous-projets
- Liens existants ou prévus avec d'autres projets traitant de problématiques similaires (contacts nationaux et internationaux)

4. Méthodologie

- Méthodes entrant en ligne de compte pour traiter le sujet (élaboration de variantes)
- Évaluation de ces méthodes en fonction de la problématique et arguments en faveur de celle proposée
- Description de la démarche empirique

5. Coordination du projet

- Composition de l'équipe: chef(fe) de projet et collaborateurs(trices)
- Composition du ou des groupes d'experts
- Principales institutions et personnes de contact (partenaires éventuels; voir aussi point 3)

6. Prestations antérieures

- Listage des travaux déjà réalisés dans le domaine concerné par les membres de l'équipe de projet

7. Programme de travail

- Calendrier énumérant les tâches à accomplir avec indication des délais et des dates d'achèvement ainsi que des responsables de leur observation

8. Plan de financement

- Budget prévisionnel détaillé avec évaluation des moyens nécessaires à la réalisation de chacune des tâches (ou phases) telles que définies au point 7.

9. Diffusion des résultats

- Moyens à mettre en œuvre pour informer l'opinion
- Listage des groupes cibles particulièrement visés et des moyens à utiliser pour les atteindre
- Estimation du coût supplémentaire engendré par la diffusion des résultats