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Risk analysis and technology assessment in support of technology development; putting responsible innovation in practice in a case study for nanotechnology†

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ABSTRACT

Governments invest in 'key enabling technologies' such as nanotechnology, to solve societal challenges and boost the economy. At the same time governmental agencies demand for risk reduction to prohibit any often unknown adverse effects, and industrial parties demand for smart approaches to reduce uncertainties. Responsible research and innovation (RRI) is therefore a central theme in policy-making.

Risk Analysis and Technology Assessment, together referred to as RATA, can provide a basis to assess human, environmental and societal risks of new technological developments during the various stages of technological development. This can help both governmental authorities and innovative industry to move forward in a sustainable manner. Here we describe the developed procedures and products and our experiences to bring RATA in practice within a large Dutch nanotechnology consortium. This is an example of putting responsible innovation in practice as integrated part of a research program, and to increase awareness on RATA and how to perform and use this by technology developers.

KEY-WORDS: responsible research and innovation, risk analysis, technology assessment

INTRODUCTION

The speed of development and introduction of new technologies into society is dazzling. Governments worldwide invest huge sums in developing 'key enabling technologies', expected to significantly contribute to solve societal challenges and boost national economies. The public sector both is an important player in stimulating and financing technology development (Mazzucato, 2013), and has a role to protect humans and the environment against –still uncertain- possible adverse effects of new technologies.

In response, much attention is paid to responsible research and innovation (Stilgoe et al., 2013, Douglas and Stemerding, 2013, Von Schomberg, 2011, Owen et al., 2012, Rip 2014), including social, sustainability, ethical and moral concerns of innovation processes. This can be defined as 'a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products in order to allow a proper embedding of scientific and technological advances in our society' (Von Schomberg, 2011). In line with this, the term 'risk innovation' was proposed to match and complement technology innovation, and to develop tools and practices that protect social and environmental values while enabling creation and growth (Maynard, 2015).

There are numerous examples of risks that were only broadly recognized after market introduction of new products or technologies, often neglecting early warnings (EEA, 2013). If there is any doubt amongst the public about safety aspects, acceptance and implementation of new technologies in society can be seriously hampered and thus potential benefits can be less enjoyed (Gupta et al., 2013). Examples of such 'contested technologies' are genetically modified organisms, genetic technology, fracking technologies for shale gas, biofuels, carbon capture and storage, etc (eg. Dignum et al., 2016, Cuppen et al., 2015).

Chemical products that are introduced on the market, are registered and evaluated for their possible risks for humans and environment before market introduction. In Europe this is regulated via legislation for industrial chemicals, biocides, pesticides, (veterinary) pharmaceuticals, cosmetics, food additives, and so on.

Comparative legislation as exists for chemicals to prevent adverse human, environmental or societal risks after market introduction, has not been elaborated for technological developments in a broader sense, apart from generic legislation on product safety (2001/95/EC). However authorities, industries, investors and insurance companies demand to address questions on risks of emerging technologies, and to decrease inherent risk uncertainties. This requires smart approaches, applicable to a broad set of technological developments, to swiftly reduce uncertainties to acceptable levels.

SOME BACKGROUND ON RESPONSIBLE RESEARCH AND INNOVATION

Responsible research and innovation, or RRI, received a prominent place in EU's policies regarding research funding and technology development. As 'cross-cutting issue' RRI is promoted throughout EU's Horizon 2020 research program. Although definitions are available (Von Schomberg, 2011, Rip, 2014), and RRI is even considered to be a buzz-word (Bensaude Vincent, 2014), a recent literature review shows that RRI is still loosely articulated and further operationalization is required (Ribeiro et al., 2016). RRI generally emphasizes to consider ethical and social aspects of research and innovation next to natural sciences, and therefore asks to combine assessments from different perspectives. To this end, the TranSTEP approach was developed which pleas for maximizing the integration of various existing assessment methodologies including, eg. TA, RA and Life Cycle Analysis (LCA) (Forsberg et al., 2016).

Responsible innovation received much attention in the context of developing nanotechnologies, related to concerns on both possible human and environmental risks and on a possible lack of acceptance (Rip, 2014. Erbis et al., 2016). Several countries therefore organized dialogues on nanotechnology (Tomellini and Giordani, 2008, Krabbenborg, 2012, Pfersdorf, 2012).

RATA; RISK ANALYSIS AND TECHNOLOGY ASSESSMENT

Both risk analysis and technology assessment, together here referred to as RATA, have a strong and long-standing scientific basis which is well applicable in the context of responsible innovation.

Risk analysis (RA) of human and environmental health effects of chemicals has it's basis in natural sciences, mainly chemistry, toxicology, ecology and statistics (Van Leeuwen and Vermeire, 2007). RA is embedded in many chemical legislations and accompanying guidance documents worldwide. RA requires data on physico-chemical properties, expected emissions, degradation, sorption, (eco)toxicity, kinetics, bioaccumulation, etc. Assessment factors are used to cope with uncertainties. Hazardous properties of a chemical are assessed for human and environmental health, based on toxicity tests with cell-based assays, organisms or cosm studies, or using quantitative structure activity relationships or read-across approaches. Depending on the chemical structure more attention can be paid to specific modes of toxicological action, such as genotoxicity or endocrine disruption. In addition, the exposure towards the chemical is assessed. For humans exposure via consumption and use, the workplace or the environment is assessed. For the ecosystem the exposure of species via the various compartments soil, sediment, water, air and by the food-chain is assessed. Exposure assessment is based on the fate of the chemical, combined with the specific emission pattern. Finally in RA, the level at which the exposure takes place is compared to the level exerting adverse effects. A tiered approach can be used, where higher tiers are more labour- and data-intensive and in which measures to mitigate exposure can be included. Life Cycle Assessment (LCA) approaches can be integrated in RA to include all impacts during the life cycle of the (nano)chemicals, i.e. the production, use and disposal phase (Grieger et al. 2012, Walker et al. 2015, Gilbertson et al., 2015, Subramanian et al. 2016).

Technology assessment (TA) assesses the possible effects and futures of a technology in society (Van den Ende et al., 1998). This includes the public's perception, different stakeholders perspectives, possible changes in responsibilities and liabilities of and between actors. Participatory methods are therefore important for TA (Burgess and Chilvers, 2002). As social impacts are viewed as core dimensions of technological development, TA seeks to shape technology and social contexts through information, interaction and dialogue (Russell et al., 2010, Fleischer and Grunwald, 2008). TA has it's basis in social sciences, mainly sociology, psychology, ethics and philosophy. TA is not embedded in legislation, but commonly used where consumers or the general public participate in the assessment (Frewer, 1999).

Used in combination, RATA can provide a scientific basis to assess human, environmental and societal risks of new technological developments and their applications, and thus can be considered as relevant for responsible innovation. This can be applied during different stages of technology development (eg. Von Gleich et al., 2008).

RATA AND NANONEXTNL

Here, we describe our experiences to bring RATA in practice in the context of nanotechnology development within NanoNextNL, a large-scale Dutch national research and technology programme for micro- and nanotechnology (www.nanonextnl.nl). Over one hundred companies, universities, knowledge institutes and university medical centres were involved, the total sum was 250 million €, and the program was running from 2010 until 2016. During the formation of NanoNextNL political attention was paid to concerns for adverse effects of nanotechnology. The Dutch parliament requested that 15% of the total budget of NanoNextNL was granted for risk and impact research, as a precondition and accelerator for innovation. Within NanoNextNL risk analysis and technology assessment were put together in one RATA theme, next to nine other themes (Walhout and Konrad 2015). Five themes gained fundamental insight into nanotechnologies, while four themes applied nanotechnologies in respectively the food, water, energy and pharma sector (Figure 1, for more information see NanoNextNL 2017).

The RATA theme was divided in three programs, focusing on human risks, environmental risks, and technology assessment. The aim was to create excellent science in support of regulation of nanomaterials. This was put in practice via participation by programme members in Scientific Committees of the European Commission, ECHA, ISO, OECD, etc. Next, the ambition was to bridge innovation with safety and society requests, by facilitating interaction between RATA and the other themes.

The main topics for the human health program were detection, exposure, bioavailability and toxicity (e.g. Bezantakos et al., 2015, Walczak et al., 2015, Kloet et al., 2015, Bekker et al., 2015, Braakhuis et al., 2015, 2016, Marvin et al., 2013). In this program, new approaches and tools are developed to describe responsible use of nanomaterials for workers and consumers, and models to prioritize nanomaterials for higher tier testing.

In analogy, the environmental health program aimed at understanding and predicting emission routes, environmental fate processes, exposure of organisms, and (eco)toxicity of nanoparticles (Kettler et al., 2014, Kolkman et al., 2013, Meesters et al., 2014, Quik et al., 2014, Velzeboer et al., 2014, Koelmans et al., 2015, Bauerlein et al., 2017). Analytical methods to determine nanomaterials in environmental matrices are developed, and models to predict environmental concentrations in various compartments. The obtained improved understanding on factors that govern environmental risks is applied to adapt tools for environmental risk analysis for nanomaterials.

The technology assessment program (Bos et al., 2013, Te Kulve et al., 2013, Alvial Palavicino. 2016, Van Giesen et al., 2015, Gupta et al., 2015) studied the dynamics of nanotechnology developments and their embedding and impacts in society, including ethics, social equity and protection of norms, public perception and engagement. This program also focused on governance questions for regulatory and ethical and moral embedding of nanotechnologies.

DEVELOPED RATA PORTFOLIO AND EXPERIENCES

Next to creating excellent science, the objective of NanoNextNL was to increase awareness on RATA by the scientists involved in the development and application of nanotechnologies which were active in the nine other themes (Fig 1), and to develop and apply tools to guide a safe design and application of nanomaterials and -technology. This to encourage that safety and societal discussions keep pace with innovation processes, and to better safeguard that developments bringing unacceptable risks are identified and adapted at early stage. Here, we describe the interaction with scientists involved in the development and application of nanotechnologies, as well as the procedures and products that were developed to enhance this interaction. In short our experiences include;

- Creating awareness of the supportive role of RATA in innovation processes
    - Two-day RATA course
    - RATA in PhD theses

- RATA masterclasses and discussions
- Safe innovation tool
    - Development of a set of RATA awareness questions to valuate ideas in various technology readiness levels
    - Application in business cases
- Societal incubator as an added feature or analogous to a business incubator

Creating awareness of the supportive role of RATA in innovation processes

Well-educated human capital is essential for responsible innovation (Sabadie, 2014). To raise awareness amongst PhD students and other scientists involved for the role of RATA in early stages of innovation, a 2 day RATA course was developed. The course has been followed by 83 persons within NanoNextNL, and focused on the basics of risk analysis and technology assessment and its potential role in early stage innovation. The purpose, concepts and paradigms of environmental and health risk analysis are introduced, and topics such as the innovation circle, public communication and ethics are discussed. Besides, attention is paid to RATA questions related to the work of the participating PhD students, in preparation of a discussion on a specific RATA question in their PhD theses. Experienced RATA scientists support defining topics to address in the respective PhD theses.

Many PhD students turned out to be highly interested in the topics discussed. Although RATA questions are often posed to them by family or friends, they are seldom discussed at the university department where the PhD students are employed. Their working environment is described by the students as a ‘protected space’, the interaction as opened by the course might help to create responsible innovation (Krabbenborg, 2015). The course increased the RATA awareness amongst the NanoNextNL PhD students, other scientists involved, and their supervisors, and their understanding on the science within the RATA research programme itself. Up to one to three years after the course, 78% of respondents to a questionnaire under RATA course participants answer that they know what RATA entails, and how to implement it in their research (unpublished data based on 134 questionnaires, based on a master thesis).

For 56 PhD students in specific programmes within NanoNextNL it was obliged to spend a section of the PhD-thesis to RATA, out of in total in NanoNextNL 225 PhD students were involved. RATA research is thus performed throughout the NanoNextNL program. In addition to the RATA course, PhD students were offered coaching by RATA scientists with expertise on their specific question, to date 10 students made use of this possibility. Many PhD students chose to shortly reflect on RATA, and especially elaborate in their own specific scientific discipline. Some elaborated examples have however been published, such as work by Mulder (2016) who used technology assessment to identify relevant applications and their characteristics for a sensor. Mulder concluded that a TA exercise is time-intensive, and most beneficial close to the beginning of the project. TA makes the researcher aware of possible opportunities, by anticipating future performance of the device. Another example is work in the water technology theme, where the treatment efficiency to remove fullerenes was studied as a way to minimize environmental and health risk (Floris et al., 2016). Some other examples are related to the socio-technical aspects of plastics for culturing IPS cells (Hulshof, 2016) or the technological aspects and social embedding for a microfluidic bilayer (Stimberg, 2014).

Finally RATA masterclasses were provided in Dutch Nanotechnology conferences, directed to experienced scientists and supervisors. In program meetings of all nanotechnology application themes, RATA was discussed in relation to the topic of the specific program. RATA theme events and specific workshops devoted to topics as ‘safe-by-design’ were open to interested scientists from other programs. Audiovisual material was developed (https://www.youtube.com/watch?v=T-mrx72qpVU). These activities helped to build an integrated network between technology developers and RATA experts, and make supervisors in general more supportive to PhD students regarding their RATA work.

Safe innovation tool

To scale-up innovations from a low technology readiness level (TRL) to a higher TRL (EC, 2014), many investments are required. RATA can be integrated to guide “stage-gate” innovation (Cooper, 2008), and in schedules and toolboxes to analyse business cases.

Based upon all discussions and interactions, we developed a set easy-to-answer questions to check the RATA awareness behind an idea (Table 1). The questions in this ‘Safety and Society check’ can be posed at different TRL levels, and answers will be more elaborate and data-rich further along the innovation chain. We incorporated questions that point to a market opportunity (RA 1-2), and questions that make the product developer more aware about legislative frameworks in place (RA 3-5). Furthermore we stimulate the developers to explicit available data on hazard and fate (RA 6-8), and to think about possible emission pathways and mitigation strategies to limit emissions (RA 9-10). Then, questions relate to the stakeholders involved, their stakes, responsibilities, liabilities and mutual relationship (TA 1-4). Finally, questions relate to societal consequences (TA 5-6). When these questions in the Safety and Society check (Table 1) are combined with common questions posed during business plan development (Figure 2), this yields a realistic insight in the possibilities to reach the market phase and the investments needed, thereby increasing the chances of a successful business.

This Safety and Society Check, including the RATA awareness questions, was applied during scanning business cases within NanoNextNL in order to challenge business development in start-ups and established companies. This learned that innovators generally have information that is also useful to screen for potential risks. This improved use of existing information reduces uncertainties.

RATA awareness aims to search for the lowest inherent toxicity and the highest functionality during the entire design phase, also to be better compatible for application in a circular economy. If the use of inherently safe materials is not possible, manners of application of the material and of product use that prevent emission might be a second best possibility. As a last and less favourable possibility, mitigation measures to prevent emissions and adverse effects can be included in the product design.

Societal incubator

Innovation processes can be hampered by ‘waiting games’ (Robinson et al., 2012, Parandian et al., 2012, Van Lente, 2015) where one actor waits for a second to make an important move. These waiting games more easily occur under high uncertainty, even if it is generally accepted that a technology is promising and further development is needed.

This created the idea of a “societal incubator” to allow experimentation and collective learning in areas of nanotechnology (Van Lente, 2015, Rerimassie et al., 2016), as analogue of and supportive to a business incubator where a research finding is guided towards a commercial product. In the societal incubator a range of pre-commercial applications are investigated for future possibilities and the variety of societal acceptance. Technology developers, businesses and civil society stakeholders and organisations can explore possibilities for innovation, emphasizing urgent societal challenges. The societal incubator stimulates reflexivity about one’s role in the novel technologies and their embedment in society (Van Lente, 2015). A societal incubator starts with a promising (nano)innovation for which there remain significant uncertainties concerning public support, policy, risk assessment, regulation and liability. In the incubator information is collected and interaction organised, this is analysed and the a decision in taken on further technology development (Rerimassie et al, 2016). During exploratory testing, it appeared that participants received the idea of the societal incubator as a positive contribution to prevent waiting games, and to shine light on their possible role in the innovation process. Actors such as regulators or consumer organisations are better able to adapt to the technological developments upfront. A societal incubator might stimulate the success rate of new developments, by offering an institutionalized protected space in which scientific and business developers, regulators, NGOs, etc. have the opportunity to communicate openly and honestly, and learn and share about specific new developments (for information on design and organization see Rerimassie et al, 2016).

LESSONS LEARNED

Although there is much policy attention to responsible innovation and research funding is allocated to this theme, we are not aware of other examples of large programs on emerging technologies where RATA has really been integrated. Within NanoNextNL, the RATA theme was both articulated in a specifically devoted theme, as well as integrated in all themes of the whole program using the described portfolio.

The goal of responsible research and innovation clearly ultimately asks for full integration of RATA within research and development programs of emerging technologies (see also Walhout and Konrad, 2015). Given that at current this full integration is still to be reached, we believe that the dual modus of dedicated RATA research and integration of RATA components across NanoNextNL (see Figure 1) that was chosen here is a good program structure. This dual modus ensures structural attention to and integration of RATA in technology development, and subsequent business and policy-making for new technologies, and seems unique in the international context (eg. Fisher and Maricle 2015).

Awareness has grown for the benefits of linking technology assessment and risk analysis activities. Technology assessment helps to gain insight in potential pathways of innovations, and identifying hurdles for innovators or regulators. In NanoNextNL, technology assessment was performed for cases in food, water, energy and medicine, which helped to identify whether a lack of information on human and environmental safety was an obstacle for e.g. investors to support the creation of start-ups.

In NanoNextNL there were programmed stimuli for the interaction between RATA and the development and application of nanotechnologies. These could however be further strengthened by paying attention to this interaction from the start e.g. in consortia agreements and financial agreements signed per program in the starting period. Integration between RATA and technology development and application in the earliest phase as possible, namely during the writing of research proposals, is a lesson to be further expanded and stimulated. Academic impetus, such as publications in highly cited journals, do not always stimulate the required multi-disciplinary approach. However, technologically oriented scientists do see the strategic advantages of spending attention to responsible innovation in their own research, such as increased funding possibilities, increased speed of implementation, and societal acceptance of their work. PhD students also feel that they are better suited for a broader variety of job opportunities (unpublished data based on 134 questionnaires).

A further possible improvement is the inclusion of design for circularity, next to safe-by-design, in the approach, eg. concerning the recyclability of material, options to disassembly etc. Although use of scarce resources, such as space and energy, were at the start of NanoNextNL not considered as relevant as the safety and society questions explored, still these relevant aspects could be integrated in following work.

CONCLUDING REMARKS

There is much policy attention to responsible innovation and research funding has been allocated to this theme. However, there are not many large programs on emerging technologies where this is really been integrated (Khan et al., 2016).

NanoNextNL offer a unique network to explore how to put this into practice, where we focused on RA and TA as important contributors to responsible innovation. Activities such as courses and discussions in program meetings helped to build an integrated network between technology developers and RATA experts and to increase the RATA awareness. Many scientists involved are highly interested in RATA topics discussed. Within NanoNextNL the RATA theme was both articulated separately in a specifically devoted theme, as well as integrated in the whole program using the developed portfolio. This dual modus is a good model to ensure attention to and integration of RATA in technology development, and subsequently business and policy-making. Linking technology assessment and risk analysis activities helps to gain insight, for example whether a lack of safety information is an obstacle for investors.

To scale-up innovations to a higher readiness level, RATA can be integrated to guide innovation and in business case analysis. RATA as integrated part of innovation intensifies interaction between innovators, RATA-scientists and regulators. A set of basic questions on RATA awareness is to be used, where answers will be more elaborate and data-rich further along the innovation chain. Innovators generally have information that is also useful to screen for potential risks.

The approach described might inspire responsible innovation also for other emerging technologies, and is advised to be coupled upfront to governmental investments in stimulating technology developments.

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DATA ACCESSIBLITY

Data associated with this research can be requested from the corresponding author by emailing annemarie.van.wezel@kwrwater.nl.

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Figure 1: Themes in NanoNextNL

Figure 2: Safety and Society Check used to challenge, improve and accelerate business development

Table 1: Set of questions to check RATA awareness

Table 1; Set of questions to check RATA awareness

What is the experience within your organization with Risk Assessment & Technology Assessment?	
Risk Assessment	*Technology Assessment*
RA1. Is your product less risky than existing products?	TA 1. Which other stakeholders, besides suppliers and customers, could you imagine?
RA 2. What are new aspects, related to already authorized products?	TA 2. How will these stakeholders be affected in both positive and negative ways?
RA 3. What is the 'nano' aspect of your development?	TA 3. How does this new technology influence stakeholders' responsibilities and liabilities?
RA 4. What is the legislative framework for market introduction?	TA 4. How does this new technology influence the relationship between stakeholders?
RA 5. Are there any discussions on 'nano' within this legislative framework?	TA 5. What is society missing out on both positive and negative effects if your idea does not reach the market?
RA 6. What do you already know on the safety aspects?	TA 6. Which different possible futures could you imagine with your development?
RA 7. Do you have any information on the intrinsic hazardous aspects?	
RA 8. Do you have information on the environmental fate and behaviour?	
RA 9. Can material be released in significant quantities during the production, use, or waste phase?	
RA 10. Could you minimize emissions?	

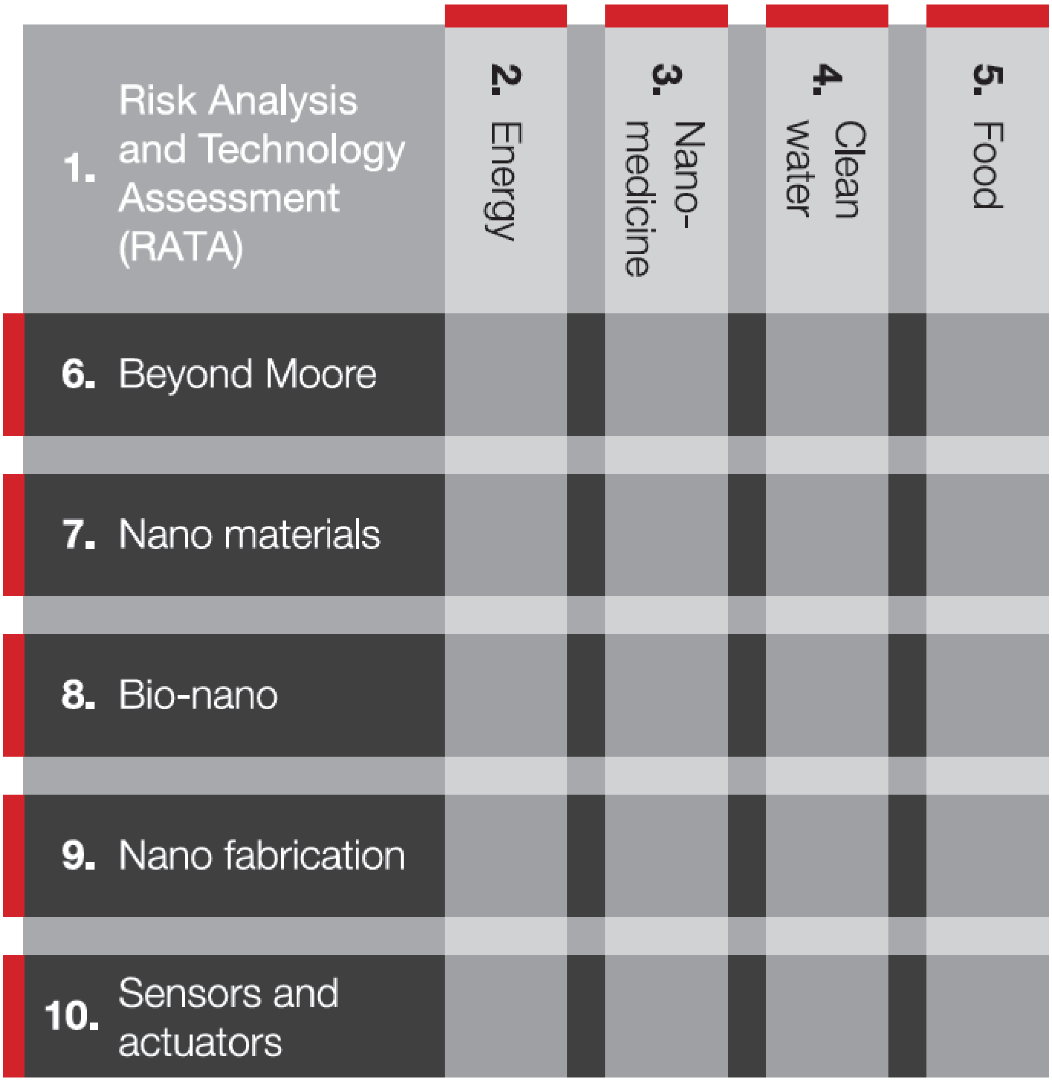
1. Risk Analysis and Technology Assessment (RATA)
2. Energy
3. Nano-medicine
4. Clean water
5. Food
6. Beyond Moore
7. Nano materials
8. Bio-nano
9. Nano fabrication
10. Sensors and actuators

Figure 1

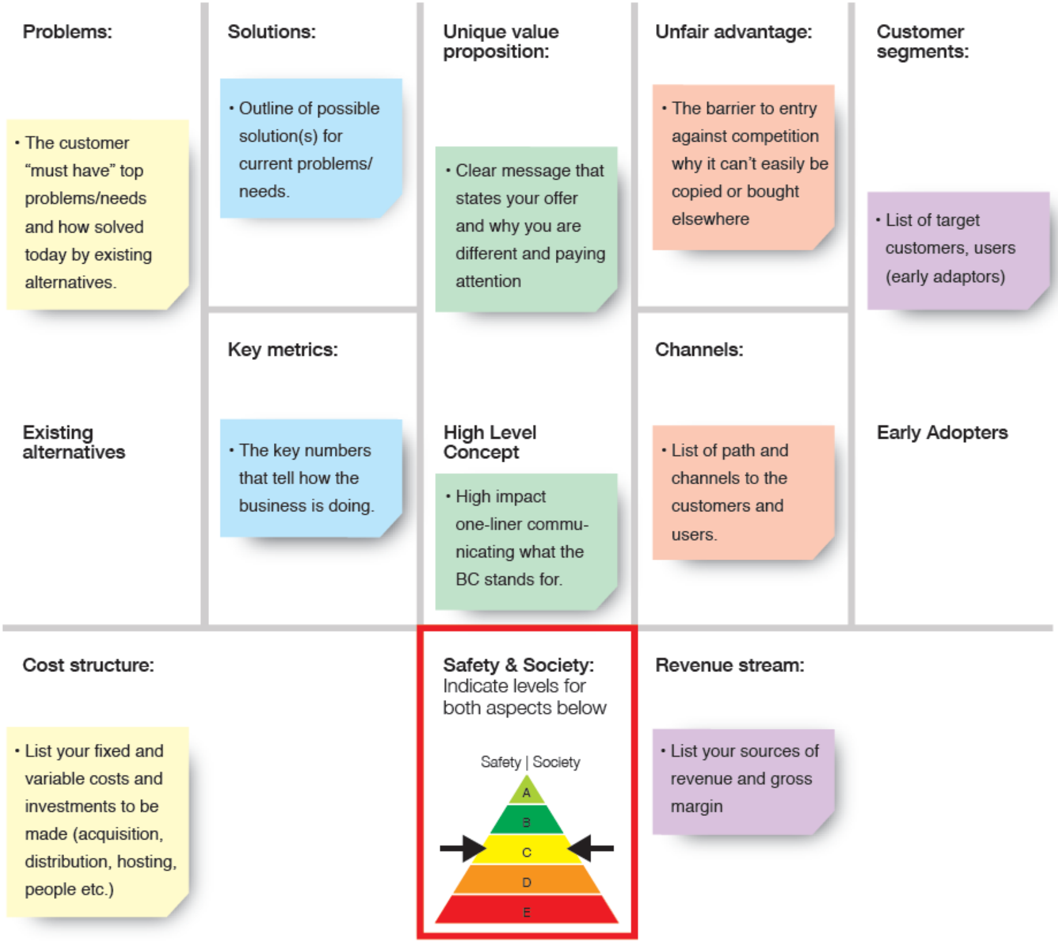
Problems:
• The customer "must have" top problems/needs and how solved today by existing alternatives.
Existing alternatives
Solutions:
• Outline of possible solution(s) for current problems/ needs.
Key metrics:
• The key numbers that tell how the business is doing.
Unique value proposition:
• Clear message that states your offer and why you are different and paying attention
High Level Concept
• High impact one-liner commu-nicating what the BC stands for.
Unfair advantage:
• The barrier to entry against competition why it can't easily be copied or bought elsewhere
Channels:
• List of path and channels to the customers and users.
Customer segments:
• List of target customers, users (early adaptors)
Early Adopters
Cost structure:
• List your fixed and variable costs and investments to be made (acquisition, distribution, hosting, people etc.)
Safety & Society:
Indicate levels for both aspects below
Safety | Society
A
B
C
D
E
Revenue stream:
• List your sources of revenue and gross margin

Figure 2