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Introduction- The impacts and expansion of technological advances, the so-called Fourth Industrial Revolution (SCHWAB, 2016), is about historical changes in terms of size, speed and scope, and the unfolding of these transformations, their complexity and interdependence yet unknown. But what is known is that the parts interested in global society - government, business, universities and civil society - have the responsibility to work together in order to better understand these emerging trends as well as to deal with the risks of these innovations in a sustainable way. The transformations of today's society are larger than it can be predicted, deeper and faster than at any other time. Thus, the current scenario presents itself as a challenge for new analyzes studies and research (ROCHA, MARTINI, 2016).

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Wilson Engelmann [α], Raquel Von Hohendorff [σ] & Daniele Weber S. Leal [ρ]

I. Introduction

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The world on the nano scale has always existed integrating nature, but only from the middle to the end of the twentieth century, the human being has been able to access this order of magnitude, visualizing the billionth part of a meter. It is observed in the quotidian human life the increasing consumption of innumerable new products with nanotechnology in the most diverse areas. Products and sectors in which it is possible to find nanoparticles are: feeding; household appliances; medicine; petroleum; printers; renewable energy; sports and fitness; textiles; agriculture; automotive; construction; cosmetics; as well as the use for environmental purposes (INTRODUCTION, 2017). Even this broad role is open due to the continuous process of development of nanotechnologies. Such products bring the promise of benefits and utilities never before thought, arousing curiosity in the consumers and society in general. Therefore, the consumption of these creations in nano scale has been increasing, with a universe of news poured into the market daily.

In spite of the significant development limits reached by nanotechnology, there is no specific regulation. According to Engelmann (2015, p.350), "... the Law should provide the basis for a normative set of accompaniment, advisement and rewards for the implementation of the most acceptable conduct in relation to nanotechnology risk management."

Because nanoparticles are very small, measuring less than a hundredth of a billionth of a meter, they are governed by physical laws very different from those with which science is accustomed. Nan particles are likely to have a higher toxicity than particles in normal sizes, which may pose risks to the health and safety of researchers, workers, and consumers.

It takes a critical Law, capable of reading reality and provoking the necessary changes in this context, under penalty of remaining isolated from other areas of knowledge, which will use the empty spaces left by Law, to act, including onregulatory issues.

The development of these technologies generates important ethical, legal and social impacts, also related to the precautionary principle and information, as well as reflexes in the labor relations and in the environment. It is impossible to imagine scientific and technological advances, and also economic, based on social regression in terms of health and protection. In

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order for the Law to be able to deal with the challenges brought by the advances of nanotechnologies, it must open itself to two paths: penetrate other areas of knowledge that may help it understand the complexity of the realities that nanotechnologies will enable and allow ideas to enter from these areas. This will be the condition of possibility for innovation in the *legal in the Nanotech Era.*

Thus, the advance of nanotechnologies, in a growing set of applications, begins to integrate the daily life of the Brazilian and world societies. On the other hand, the research and products that will come from this human intervention in the natural forces will require the performance of different systems, with the evaluation of the emerging social, ethical and regulatory impacts supported by a model of innovation that should be responsible and sustainable, once there is uncertainty about nanotechnological risks.

For the development of this article it will be used the systemic-constructivist method which considers reality as a construction of an observer, analyzing all the peculiarities implied in the observation. It is a method which starts from a complex second-order observation, presupposing reflections that are established from a set of theoretical categories, characteristic of the Pragmatic-Systemic Matrix, maintaining a theoretical self-referential coherence. It is an autopoietic strategy of juridical reflection on the conditions of meaning production, as well as the possibilities of understanding the multiple differentiated communicative dynamics in a complex environment, such as the one generated by nanotechnologies.

Moreover, this approach presupposes the understanding of Law as an autopoietic social system, whose operations are communicative, developed through decision-making processes elaborated within a certain legal organization.

It is from the systemic-functionalist perspective that this connection between the problem and a solution to be constructed is sought, notably by observing the normative frameworks capable of addressing the challenges brought by nanotechnologies. This method is conducive to the development of the movement that goes from the interdisciplinary to transdisciplinary attempts, since it intends to deal with the action of several levels of reality, of diverse semantics.

II. Presenting the Nano new World

> *"The changes are so profound that, from the perspective of the history of mankind, there has never been a moment so potentially promising or dangerous" (SCHWAB, 2016, p.12).*

The Fourth Industrial Revolution, which has been occurring since the turn of the century, deals with technological innovations such as artificial intelligence, robotics, the internet of things, autonomous vehicles, 3D printing, nanotechnologies, biotechnology, energy storage and quantum computation. What distinguishes it from the three previous revolutions is speed, breadth and depth, as well as the fusion of technologies and the interaction between physical, digital and biological domains. (SCHWAB, 2016). As for velocity, it evolves at an exponential and non-linear rhythm, as a result of the multifaceted and deeply interconnected world in which we live; in terms of breadth and depth, based on the digital revolution and combining various technologies, generates unprecedented paradigm shifts not only in the economy but also in society and individuals. Also, regarding the *systemic impact*: it involves the transformations of entire systems between and within countries, organizations, industries and in all society (SCHWAB, 2016).

Nanotechnology is the set of actions of research, development and innovation, obtained due to the special properties of matter organized from structures of nanometric dimensions. The term nanotechnology derives from the Greek prefix *nános,* which means dwarf, *techne* that equates to craft, and *logos* that expresses knowledge. Currently, nano-scale carries many uncertainties, especially concerning risks that are highly harmful to health and the environment (DURÁN, Mattoso, 2006).

Nanotechnology exhibits a high degree of interdisciplinarity. Biologists, chemists, physicists, physicians and engineers contribute with their experiences and ideas to generate innovative applications and products for society. This requires intensive collaboration based on division of labor and a high level of understanding of other disciplines (GERMANY, 2016).

As it often occurs with innovations, it is difficult to know where advances in new materials could lead the world. A new material on the nanoscale, such as graphene, which is about 200 times stronger than steel, million times thinner than a human hair and an efficient conductor of heat and electricity (ISAIAH, 2015), when it becomes financially competitive (gram for gram, it is one of the most expensive materials in the world; 1 micrometer costs more than $ 1,000), it may cause disruptions in manufacturing industries and infrastructure (LASKOW, 2014).

On the one hand, it is still unknown the ramifications of the modifications generated by these revolutions, but on the other hand, the complexity and interconnection between sectors imply that all the actors of global society - governments, organizations, academia and civil society - need to work in order to better confront reality, and thus shared knowledge becomes a *sine qua non* condition for this new future to be faced (Schwab, 2016).

The term *nanotechnology* has raised controversies about the measures that should be considered for the categorization of a product or

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process being worked at the nano scale. Therefore, it is necessary to start from a standardization and thus, adopt the definition developed by the *International Organization for Standardization* (ISO) - ISO /TC 229 in which two fundamental characteristics are verified: (a) products or processes which are typically, but not exclusively, below 100 nm (one hundred nanometers); and b) on this scale, the physicochemical properties must be different from the products or processes that are on larger scales (ISO / TC 229, 2005).

To illustrate this scale, a human hair strand is between 10,000 to 100,000 nm, a single red blood cell has a diameter of about 5000 nm, the viruses usually have a maximum size of 10 nm to 100 nm and a deoxyribonucleic acid molecule (DNA) has a diameter of about 2nm. The term *nanotechnology* can be misleading since it is not a single technology or scientific discipline. Instead, it is a multidisciplinary grouping of physical, chemical, biological, engineering, and electronic processes, materials, applications and concepts in which the defining characteristic is size (ISO, 2017).

Nano is a measure, not an object, that is, it encompasses "the ability to work at the molecular level, atom by atom, creating structures with different molecular organizations and exploring the new properties exhibited at such a scale" (Engelmann, Cardoso, 2010), whose particles correspond to the order of 1-100 nanometers (equivalent to 0.000000001 meters), which cannot be seen with the naked eye.

These technologies correspond to research and technological development at the atomic, molecular or macromolecular level in a scale ranging from about one to one hundred nanometers in any dimension; the creation and use of structures, devices and systems that have new properties and functions because of their small size; and the ability to control or manipulate matter on an atomic scale (United States, 2007).

Invernizi et al. (2016) conducted researches on the contributions of Latin American investigations on nanotechnology, focusing on medicine, energy and water, and showed that the information analyzed reveals great regional disparities, with a strong concentration of activities in Brazil, and then Mexico, which are the major countries with systematic scientific trajectories. In an intermediate situation are Argentina, Chile and Colombia tending to strengthen their knowledge and several other countries with more fragmented competencies. Nevertheless, the data shows a weak regional collaboration, more bilateral than in the network. In fact, international agreements could stimulate networking projects around key issues with a general social impact for all countries in the region.

Investments in Brazil are currently increasing. In the national panorama, it is verified the study conducted in 2015 through the publishing of the Institute of Applied Economic Research (IPEA), coordinated by Marcial – in which it is discussed the *World Megatrends for 2030*, with the current questions about what entities and personalities think about the world - a raise in investment and application in the field of nano-technology and biotechnology has been observed (MARCIAL, 2015).

> By 2030, there will be the maintenance of the technological revolution, integrating biotechnology, nanotechnology, TIC and technologies of materials in a fast speed. Advances in areas such as new materials and bioengineering are changing pharmaceutical and medical care principles when it comes to innovations in products and services for human health. In the field of medicine, especially in developed countries, there is a high probability of a strong advance in gerontology and genetic technologies, using nanochips and microsens or technology, organ transplants, nerve cells, retina, etc., which will allow a substantial increase in the average human life (Rockefeller Foundation and GBN, 2010). Technological convergence can also be observed in the energy field [...]. However, the pace of technological change is difficult to predict and some new technologies need further study and investment strategies given their potential impact on human development. Examples of these are the use of biotechnology and nanotechnology in energy generation (European Commission, 2011). Everything indicates, for example, that solar energy will be much more efficient in the future. This efficiency will occur due to advances in materials used, including polymers and nanoparticles. (Marcial, 2015).

A team from the *University of Central Florida* (UCF) has developed a new hybrid nanomaterial that harnesses solar energy to generate hydrogen from seawater that could be used for a new source of clean-burning fuel while alleviating the demand for fossil fuels. The researchers used a photocatalyst - a material that stimulates a chemical reaction using light energy and durable enough to handle the biomass and corrosive salt of seawater. In order to achieve this new fuel, they used a catalyst that not only harvested a much wider spectrum of light than other materials, but also withstand the harsh conditions of seawater (Nanotechnology, 2017).

Producing a chemical fuel from solar energy is a better solution than producing electricity from solar panels because electricity must be used or stored in batteries that degrade, while hydrogen gas is easily stored and transported. Researchers will now focus on expanding manufacturing and improving performance (Nanotechnology, 2017).

Another example of creating new materials comes from the University of Tokyo. By combining the same Prussian blue pigment used in the works of the popular period artist (Hokusai) and cellulose nanofiber,

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a paper raw material, a research team at the University of Tokyo was able to synthesize composite nanoparticles containing organic and inorganic substances. This new class of organic/inorganic composite nanoparticles is capable of selectively adsorbing, or collect on the surface, radioactive cesium. The team later developed sponges of these nanoparticles that proved to be highly effective in decontaminating water and soil in Fukushima Prefecture, exposed to radioactivity after the nuclear accident on March 2011 (VIPIN, 2016).

It can be observed that the innumerable possibilities of creation with new materials are incredible and seem to be fictional.

Two of the most common nanoparticles are titanium (TiO2) and silica (SiO2). Rashwan and Sereda (2016) report modifications of their surfaces with organic and inorganic groups that significantly improve the usefulness of these materials as ingredients in sunscreens and toothpastes. Thus, the functionalization of titanium and silica nanoparticles improve their adhesion to human dentin, with possible applications for the treatment of dental hypersensitivity by occlusion of dentinal tubules and remineralization porters and other active components. In addition, organic and inorganic modifiers may also suppress photo degradation and facilitate the use of modified silica and titanium in sunscreen formulations.

About the use of nanotechnologies in cosmetics, a theme that attracts attention when it is verified that Brazil is the third largest consumer of these products in the world, the research group JUSNANO, Unisinos, led by Professor Engelmann produced an excellent material (book and story in comics) to spread the word.[2]

In the area of food and agriculture the innovations are also surprising. Cheng et al. (2016) review several researches and development studies involving nanotechnology in agriculture. For example, in soil management, reported applications include nanofertilizers, soil binders, water retention aids, and nutrient monitors. In plants, nanotechnology methods provide DNA for plant cells, improve nutrient absorption, detect plant pathogens, and regulate plant hormones. In animals, the nanocapsules deliver vaccines and improve the delivery of nutrients. Numerous post-harvest applications are reported, including the generation of nanocellulose from agricultural waste. Similarly, in the food-related area, nanotechnology is actively exploited (for example) in food packaging, nanocarrier systems for nutrients and supplements, nano-food additives for food and feed, nanofilms in food contact surfaces, nanosensors for food labeling and water decontamination.

In this panorama, several characteristics of nanotechnologies emerge, such as: the unusual properties of nanoparticles are mainly based on their size at nanoscale and their surface area. As the size of a particle decreases and approaches the nanoscale, many properties begin to change compared to the same material in its macro size. The color and melting temperature of gold, which are very different in nanoscale than in conventional gold, are given as an example. The toxic effects of materials that are shown as inert on the macro scale are also very different on the nano scale. As the surface area of particles increases a greater proportion of their atoms or molecules start to be displayed on the surface, rather than the interior of the material. There is an inverse relationship between the size of the particles and the number of molecules present on the surface of the particle. The increase in surface area determines the potential number of reactive groups on the particle. Changing the physical-chemical and structural properties of nanoparticles with a decrease in size may be responsible for a number of material interactions that may lead to toxicological effects.

The wider the use of nanoscale in industry, greater the number of products made available to the consumer. What is the cause of the concern? By means of specialized equipment, in conditions of interacting with the atomic level, products with physical-chemical characteristics different from those found in its similar in the macro scale are generated. Allied to this aspect, there is no specific regulation for nanotechnologies throughout the life cycle of a nanomaterial.

III. Nanotechnological Risks

The risks are largely unknown and future damage uncertain, but the decision needs to be made in the present, through the use of these new tools arising from the incorporation of the idea that knowledge can no longer be trapped within the tight limits of each field of knowledge. In this way, it is at this time that juridical models permeated by both certainty and uncertainty in relation to social expectations that are continually frustrated/satisfied through the social complexity which is constantly increasing (ROCHA, Martini, 2016).

Therefore, the point is not to not decide, but rather to promote more research to create a path from risk to security, even though practice shows that the more it is known and the more complex calculations can

[2] In a project with support from FAPERGS, between 2013 and 2015, a book was produced containing the results of the research project. ENGELMANN, Wilson (Org.). Nanocosmetics and the right to information: building the elements and the conditions to approximate the techno-scientific development at the nano scale of the need to inform the consuming public. Erechim: Deviant, 2015. In addition to this book, a comic book story was also produced, showing, through a language accessible to the layman and in a playful way, the characteristics of nanotechnologies applied to cosmetics, their risks and regulatory possibilities. ENGELMANN, Wilson. Nanotechnologies in cosmetics. Erechim: Deviant, 2015. (Nanotechnologies in cosmetics, n.5). Comic book.

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be elaborated, more aspects are known and with them more uncertainties arise and, consequently, more risks (Luhmann, 2006).

The present moment lived by the human community brings novelties and challenges, many of which are unprecedented and therefore there are incalculable consequences - positive and negative. Undoubtedly, human creative imagination permits the projection and development of artifacts that can be very useful, enabling a more comfortable life. However, the motor of the imagination - which has been called innovation - has conducted the human being to enter fields, always existing in nature, but accessible to them precisely as a result of their *disturbing human nature.*

Although the benefits of nanotechnology today dominate our thinking, the potential of this technology for undesirable results in human health and the environment should not be underestimated, hence, because of size, materials are governed by physical laws very different from those with which the science is accustomed to, opening possibilities for the nanoparticles to present a higher degree of toxicity than in larger sizes, this is the reason why there is a need to evaluate the risks that exist due to the manipulation, development and application of these new technologies, taking into account toxicity, appropriate methods for toxicity testing, as well as impacts on human and environmental health (HOHENDORFF, ENGELMANN, 2014).

An increase in publications and research on the risks of nanoparticles has been occurring (Kulinowski, 2015) and this set of publications should also be considered because they represent what is already known about the behavior of some particles when manipulated at the nanometer scale. By 2008, the US federal government was injecting nearly $60 million a year into health research and the environmental impacts of nanotechnology. In 2016 US federal agencies proposed to invest $105.4 million in research to understand and address potential risks to nanotechnology for the environment and health. This represents a massive 80% increase over the previous eight years, reflecting actual concerns about the potential hazards of purposely designed and engineered nanoscale materials (MAYNARD, 2016).

The current situation of nanomaterials and nanotechnology in relation to toxicology is uncertain and complex, as it demands solutions that use the current knowledge available to mitigate risks, while at the same time focusing on the learning of essential variables that affect exposure, toxicity and risk. The ecological and social impact of the technology results from the use of several products already marketed and discarded in the environment (BERTI, 2016). The effects of nanoparticles on humans and the environment are complex and vary based on the properties of the particles as well as on chemical toxicity. However, in contrast to rapid research and development of new properties, materials and possibilities of nanotechnologies, the research to support comprehensive risk assessments is often delayed. There are concerns about the larger surface areas and different forms and interactivity that some nanomaterials possess - which can make them react differently to their *macro, meso* or *micro* counterparts. Because of their small size, biological barriers are not always an obstacle for nanoparticles - such as the blood-brain barrier or the placental barrier between mother and fetus. Practically speaking, measuring and quantifying nanomaterials in real situations is a challenge. In most cases, they are not directly detectable by regular analytical methods because of their very low concentration in the body and/or environment studied. And even if detected, there are difficulties in differentiating between naturally occurring nanomaterials and engineered ones. In addition, most *in vitro* and *in vivo* studies conducted so far are only short-term studies, while the impacts on human health and the environment are in many cases more likely to occur after a long exposure. Consequently, there is an urgent need for long-term exposure studies (EUROPEAN COMISSION, 2017).

The use of an adaptive approach with interactive analysis of increasing levels of understanding, skill and quantization present an important evolution in the assessment and risk management of nanomaterials. With this, throughout the time it is possible to adapt new information and decisions about uncertainties, in order to identify and prioritize necessary actions on nanotechnological risks to health and the environment. This adaptive life-cycle assessment approach was developed for decision-making in processes that have an environmental impact, and it is inherent in its nature to establish a win-win condition for economic, environmental and social aspects, also called the sustainability tripod (BERTI, 2016). Thus, thinking about the idea of the principle of sustainable development, the economic relations of a society must necessarily attend to an ecossocial behavior, and consequently the business activities at world level need to be managed as they were in the ancient Hellenistic civilizations, not spending more of what is possessed, neither removing from nature more than can be restored (CATALAN, 2008).

IV. Use of Safe by Design for Risk Management

Risk mitigation strategies may be focused on reducing particle toxicity or reducing exposure, or preferably both. In addition, exposure can occur through different paths: direct exposure (occupational, consumer and/or environment) or indirect exposure (general exposure of the population through the environment), each with its own mitigation measures.

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Thus, different mitigation measures can be applied and grouped into three different general strategies (STONE, 2017):

a) *Safe by design*: design and synthesis of safer materials (less hazardous, more compatible with the matrix, less persistent in the environment) without affecting its main functionalities;
b) Occupational exposure control: reducing potential exposure of workers by using measures that reduce the concentration of particles in the workplace or by using personal protective equipment;
c) waste management: reducing the potential for environmental exposure (and exposure through the environment) by applying new and known waste treatment processes, including proposals for the implementation of recycling strategies.

The *Safe-by-design* approaches seek the *re-design* and refinement of nanoparticle materials to mitigate their potential risk while maintaining the desired properties that make them attractive for various purposes. This involves:

a) Identification of the characteristic(s) that makes nanomaterials potentially toxic;
b) Evaluation of the desired properties and how they are correlated with the resources of the identified nanomaterials;
c) Re-design of the synthesis strategy in terms of composition, morphology, structure and surface chemistry of nanomaterials. (STONE, 2017)

Safety by *design* strategies based on the surface engineering of nanomaterials has the real possibility of controlling the exposure and potential of risk, attenuating the occupational risk. From this point of view, SbD is more a risk management approach than a risk assessment approach, however, it can exist and be developed only if the characteristics of the nanomaterials that influence the release, exposure, destination/ kinetics, risk and bioaccumulation have been identified with as much information as possible (STONE, 2017).

One of the guidelines of the project Horizon 2020 from the European Union is the NMBP-15-2019: *safe by design* (katalagarianakis, 2017), from science to regulation: metrics and key sectors, whose specific objective is to make it clear that risk management involves risk quantification (toxicity) and exposure and take the necessary steps to reduce the risk to acceptable levels, ideally at an early stage in the development process of nanotechnology *(safe by design)* in various industrial sectors, but in particular for structural or functional materials, coatings and cosmetics and areas of pharmaceutical and health technology that are already currently looking for ways to mitigate the potential risks of nanomaterials and products containing nano. The challenge now is to refine existing methods for monitoring and modeling physicochemical properties and assess the biological effects of nanomaterials under relevant conditions of use, including in matrices relevant to the product. Furthermore, *safe-by-design* is expected to reduce risk and exposure through the project to an acceptable level of risk without affecting material performance and guiding the development of safer products at different stages. Specific cooperation is planned in this area with the European Union and the USA through the NNI, in which the legal, policy formulation and responsible research and innovation aspects must be integrated. The expected impact is that safe by design is used from the early stages of nanomaterial development processes; that workplaces improve quality and ensure maximum economic performance in parallel with acceptable levels of risk; that occur control and mitigation of exposure to the acceptable level of risk after the release of nanomaterials from products; and that low-cost techniques for the development of an integrated, exposure-oriented risk assessment and associated post-use monitoring *design* are developed and validated.

It is the responsibility of product developers to be aware of the efficient means of controlling the quality and safety of their products and services, but also that there is a concern with market goods that meet "[...] not only requirements and desires of the consumers but also guidelines, principles and practices connected to the diminishment of the negative impacts on the quality of the environment and its components."(SANTOS, PEREIRA, 2017). And this is a way of demonstrating the task of *safe by design*: communication between Law and Science, so that nanotechnological risks are better understood and therefore better managed, aiming at the development of nanotechnologies towards sustainability.

It can be said that *safe by design* then aims at producing safer nanomaterials, applying the best available technique (as a way of applying the precautionary principle), identifying uncertainties and risk potentials in very early stages of product development, active management for the reduction/ elimination of potential nanotechnology risks, transparency regarding data and information relevant to safety, and can also be considered an excellent *marketing* tool for the safety and concern of producers in relation to consumers and the environment, seeking for sustainability.

From an organizational perspective, Figure 1 clearly demonstrates the advantages of applying the *safe by design* tool:

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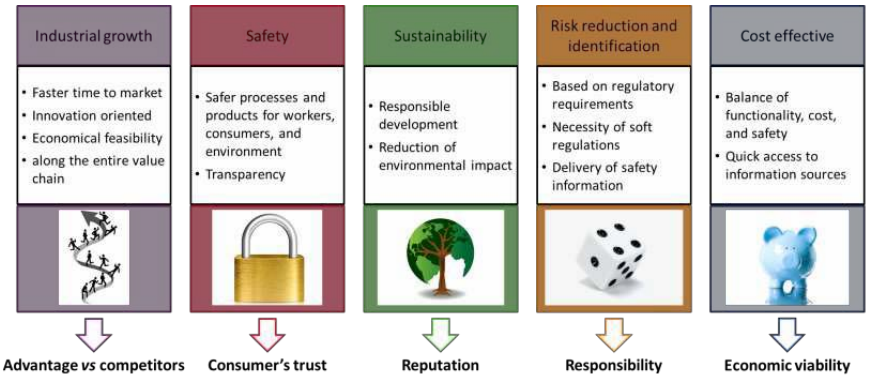


Source: Skentelbery, 2017.

Figure 1: Advantages of the application of SbD (organizational perspective)

As it is clear in the image, the main benefits for an entrepreneur who uses this tool can be characterized as such: reducing the time needed for product research and development, since it considers safety from the outset, the economic issue, the effective cost of innovation, the speed of product development to be released to the market, and throughout the development of the product the safety aspects were considered, the manufacturing of safer products and therefore more accepted by the consumer market as well as the preparation for future regulatory challenges, since the best available technique was used. It is also necessary to consider that this image was used in a context of a webinar for entrepreneurs, promoted by the Association of Nanotechnology Industries (NIA) (SKENTELBERY, 2017).

Figure 2 demonstrates some of the advantages of the *safe by design* tool from the perspective of different observers and was also presented in the same event



Source: Suarez-Merino, Schlotter, Höhener, 2017.

Figure 2: Benefits of using safe by design

It should be noted that the advantages range from economic issues, balance between cost, functionality and security, through the issues of risk and information, the issue of transparency, aspects more oriented to the entrepreneur[3] who adopts this tool, until reaching sustainability, through the development and reduction of the impact on the environment.

Consumer acceptance of different applications of nanotechnology is likely to be a determinant key

[3] According to Weyermüller, "one should not expect purely environmentalist attitudes from economic agents because the market is embedded in a system that proves to be incompatible with the principles governing environmental science. Attitudes based on environmental policy, when taken are certainly with the intention of terms of carefulness with the environment is part of the same systemic logic that takes elements from the environment, transforms them and sells them with the main objective of being economically feasible and sustainable. " WEYERMÜLLER, André Rafael. Water and environmental adaptation: payment for its use as an economic and legal instrument of protection. Curitiba: Juruá, 2014, p. 420-421.

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which will influence its future development and implementation path. The potential economic and social benefits of nanotechnology may not be realized if the social responses to its application are not adequately addressed early in the product development process. Consumer preferences and priorities in implementing regulations to optimize consumer and environmental protection and the potential characteristics of consumer products should be duly evaluated when formulating regulations, policies and *design* issues related to nanotechnology (GUPTA,FISCHER, FREWER, 2015). Figure 2 demonstrates this consumer concern as well as how much the use of the *safe by design* tool signifies the transparency of the safety issue throughout the project.

V. Conclusions

The emerging area of nanotechnology offers promises for the future. In order to make this kind of focus on preventive design occur, a cultural transition will be required: chemists and material developers need tobe educated in health, safety, and the environment; in order to make environment, health and safety become quality concerns in the development of new materials, equal to economic and performance considerations; research on the sustainability of materials must be funded at sufficiently significant levels to identify early warnings; and that regulatory systems provide incentives for safer and more sustainable materials.

It is crucial that the communication on nanosafety encourages the translation of new safety-related findings into industrial concerns with business philosophy so that the promotion of the concept safety *design* can be easily explained and accepted by different stakeholders including the general public. This is an important area of research and innovation, but its results should not be obscured by poor communication.

The social and environmental responsibility aspects of the organization also permeate the idea of *safe*in order to place on the market a safer product. The carefulness with the environment and humans through the adoption of risk management and precautionary behavior can be seen in the way organizations behave towards their consumers and the community in which they are embedded. Successful organizations should take a comprehensive view of risk management, which may consider how to protect themselves from some risks, which risks should be explored and how to exploit them (DAMODARAN, 2009).

Organizational ethics has a direct and indirect role in building economic development and its influences cover a wide range of issues, including "[...] environmental protection and sustainability; the strengthening of human rights together with the aim of eliminating poverty ... "(SEN, 2007, p.53). Castells (2007) contributes with the debate about the organizational ethics exposing that in the organizations the application of the ecological conscience in the business process is also discussed, going through the entire process of production. This is a problem of conscience, not of technical difficulty. And in that sense, in the final analysis, it is an ethical question. Antonik (2016, p.214) explains that social and environmental responsibility can be understood as "[...] everything that involves factors related to society and the environment. In the business area, it is the responsibility of the organization towards society and the environment, in addition to its legal (*compliance*) and economic-financial commitments." (author's emphasis).

Thus, changes emerge for the model of citizen organization, concerned with responsible research and innovation and with ethical, legal and social aspects, with a more sustainable evolution. These are structural changes that lead from hierarchy to co-responsibility; a change in organizational culture; the ethical reconfiguration of the world of work, as a requirement to deal with the uncertain and unknown risks that nanotechnologies can bring and the repositioning of the social balance, which not only represents the economic balance of the organization, but "[...] also data about the degree of satisfaction that a company is generating inthe society in which it is developing its activity"(CORTINA, 2005, p.85-86).

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