An Evolving Approach to Nanobiotechnology: More Confident but Still Highly Uncertain

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Introduction. The rapidly expanding field of nanotechnology and its intersection with other sciences, particularly biology and chemistry, may become a decisive factor in overcoming many limitations in biomedicine and eventually result in the appearance of revolutionary treatment methods. However, although both research and development of nanobiotechnology receive a growing governmental support, the application of such advanced technology in everyday life is often perceived with a high degree of uncertainty by the public. By discussing current trends in both social and legal "nanobio-awareness", the paper suggests that the evolution of the overall approach is possible only in a gradual, scientifically-based way.

Methods. For the purpose of this research, the following sources of information were assessed: national and supranational governmental strategies on research and development; relevant legislation with regard to the marketing of products involving nanobiotechnology (public law); extensive surveys throughout Europe and the US, carried out by scientific centres or teams of scientists. Also, works of leading scholars in the field of synthetic biology, law, risk regulation, bioethics as well as sociology were assessed with a view of identifying the dynamics of general approach to nanobiotechnology.

Results. The concept of applying nanoengineering in biomedicine is not entirely new – it was originally presented by an American physicist, Nobel prize winner R. Feynman in the late 1950s and subsequently developed by many renowned scientists in the 1980s – 1990s [1]. Since these early stages, nanobiotechnology has taken a significant step forward. For example, the toolbox for today's nanobiotechnology presents an impressive and sophisticated set of materials and particles, including gold and silver nanoparticles, self-assembling nanoparticles, magnetic and superparamagnetic nanoparticles, dendrimers, carbon nanotubes, fullerens and many more [2]. These particles play an increasingly important role in drug delivery, biomaterials, *in vivo* imaging, *in vitro* diagnostics, active implants, etc. and used in treating or diagnosing different diseases and health disorders, such as fungal infections, tumours, diabetes, etc [2]. Notably, the largest share of today's global market of nanomedicine consists of central nervous system products, anti-infectives, anti-inflammatories, anticancers and cardiovasculars, with the market itself reaching $43.2 billion in 2010 and $50.1 billion in 2011 and expected to grow to $96.9 billion by 2016 [3].

Furthermore, achievements in nanobiotechnology are well reflected in the intensive governmental support of "nanobio" research projects, the inclusion of the

latter in the long-term strategic development programmes, the rapidly growing number of inventions and patents, and, of course, billions of Euros funding on further research [4]. Thus, for example, research and development of nanobiotechnology are prioritized at the EU level in the Framework Programme for Research and Innovation 2014 – 2020 (Horizon 2020) [5]. Furthermore, many states worldwide, including the EU members, carry out national "nanobio" programmes with the similar objective to achieve significant progress in the development of nanobiotechnology and thus gain certain advantage over other economies in terms of competition on the global market of advanced emerging technologies [6]. At the same time, due to particular reasons, which are discussed below, regulatory and social stance of the application of nanobiotechnology in real life remains highly uncertain [7].

Discussion. The unique feature of nanobiotechnology is the physical properties of the nanoparticles involved, namely their size, which enables these particles to enter different body parts, inaccessible for bulker particles and traverse the blood-brain barrier, which is essential in targeted drug delivery [4]. Moreover, the large surface area of nanoparticles, combined with their tiny size increases the reactivity of such particles, which means that they may be absorbed much faster by the body tissues [4]. However, apart from the potential benefits of this startling new technology, it is precisely its unique properties, which bring a certain degree of concern and overshadow the application of nanobiotechnology in real life. This concern is primarily related to nanoparticles' safety and is based on yet fully undiscovered toxicity effects of such particles [8]. On its part, the scientific uncertainty leads to regulatory uncertainty, thus specific rules on the practical application of nanobiotechnology are just at their initial development stage. For example, in the EU, specific provisions addressing the use of nanomaterials in cosmetics were developed in 2009 [9], while a recommendation on the definition of nanomaterial was adopted by the European Commission only in 2011 [10]. At the same time, specific EU rules on nanomedicinal products are still lacking. This signifies that the governmental perception of challenges posed by nanobiotechnology has improved to some extent but the regulatory framework itself remains quite inconsistent, meaning that governments often tend to adapt a "wait and see" approach and react only in case of strict necessity [7]. This approach is not adopted by the EU alone though; similar trends are inherent in many other jurisdictions as well [7].

Still, it is possible that governments might pay more regard to public opinion rather than scientific evidence, thus the former might turn out to be a major factor in shaping the approach to nanotechnology in general [7]. However, public perception of nanobiotechnology proves highly ambiguous. First of all, the general lack of public awareness about this technology and its implications, witnessed by many researchers in the last decade [11, 12, 13] has not substantially improved after 2010 even in economically and technologically advanced countries such as the US [14] (Fig. 1).

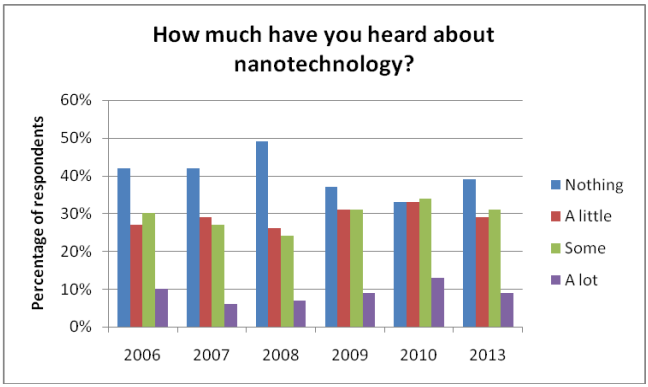

Fig. 1. Changes in public "nano-awareness" in 2006 – 2013 in the US. Based on the results of surveys carried out by Hart Research Associates [14]

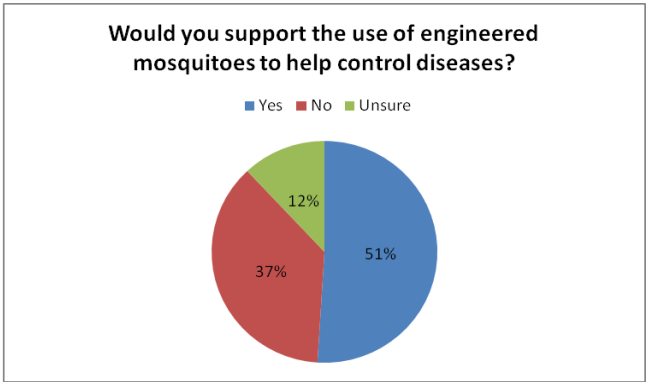

Fig. 2. Breakdown of responses to the support of using engineered mosquitoes to control the spread of diseases. Based on the results of a survey carried out by Hart Research Associates [14]

Naturally enough, the lack of knowledge may easily result in increased suspicion and, eventually, rejection [15]. However, in case of research and potential application of nanobiotechnology, surveys in the US and Europe have demonstrated a surprising trend: even though the majority of respondents showed high ignorance in "nanobio"-related topics, many of them welcomed the idea of applying nanotechnology and other advanced technologies for biomedical purposes, ignoring the potential risks [11, 14, 16] (Figs. 2, 3). These responses, of course, may likely be an outcome of high public expectations of advanced medicine, which is often perceived as a potential salvation from many severe maladies (for example, cancer) and even as the only viable way of prolonging life well beyond the average human lifespan [15].

On the other hand, public "nanobio-awareness" may not necessarily lead to the embracement of this technology. Thus, the above-mentioned studies demonstrated that knowledge of the potential risks may dissuade the public from supporting the application of nanobiotechnology, including its use in healthcare [14, 16]. Furthermore, with additional information provided on the potential risks and benefits, the latter may easily come off second-best and give way to growing concern in public's eye [14] (Fig. 4). At the same time, it should be emphasized that despite the concerns over the toxicity effects of nanoparticles on human health and environment, neither any nanotechnology-derived disasters nor any revolutionary breakthrough in medicine has yet occurred, thus the overall shaping of public's attitude towards nanotechnology risks/benefits ratio is by far incomplete [16] and may be strongly influenced by the activity of different biased advocacy groups [7]. Therefore, a cautious optimism towards the future may be the only reasonably positive public response [14, 16].

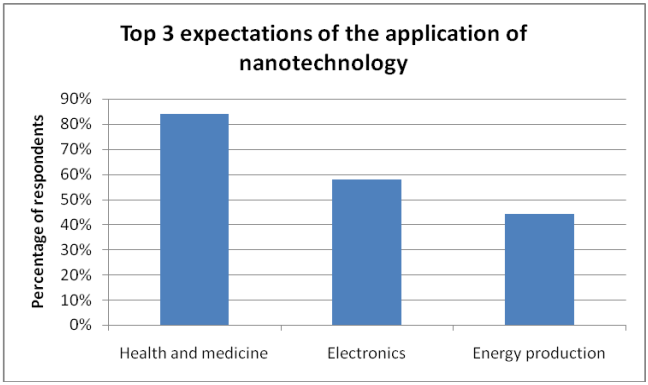

Fig. 3. Three main fields, expected to benefit from nanotechnology, according to Italian respondents. Based on the results of a survey carried out by Bottini et. al. [16]

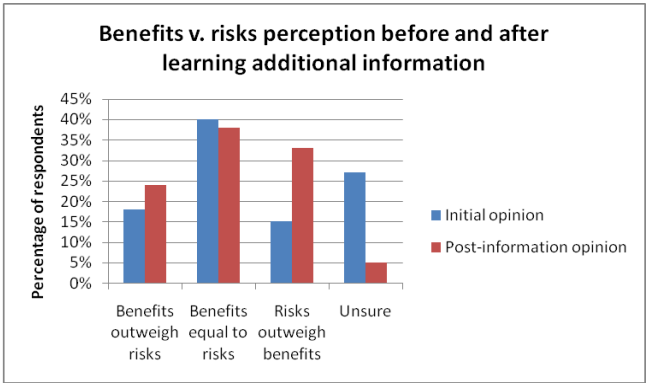

Fig. 4. The respondents' views on risks/benefits ratio of synthetic biology before and after they learned additional information about it. Based on the results of a survey carried out by Hart Research Associates [14]

Given that, it should be acknowledged that the best way to nurture prudent and unbiased public awareness is through additional education, supported by the government [7]. Coupled with increased support to scientific research that would enhance our current knowledge on the risks and benefits of nanobiotechnology, this policy would eventually bring up a truly adequate approach, helping to shape the future of this advanced technology [7].

Conclusions. As of today, public and governmental "nanobio-awareness" is not yet fully shaped. Legislators, initially supporting the research of such technology are bound by the current state of art and are only making first steps in addressing the application of nanobiotechnology specifically. Public perception is even more ambiguous, with the last few years making little difference in terms of the development of a clear opinion. Evidently, the evolution of "nanobio-awareness" into an unbiased and purely scientific approach is possible only through further active support and promotion of education as well as scientific research.

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Although nanobiotechnology may be an invaluable tool in revolutionizing contemporary medicine, our understanding of "nanobio"-related risks/benefits ratio is still very limited. Despite the increasing investments and support, the comprehensive scientific evaluation of this technology has not yet been carried out, thus its full effect on humans and environment remains undiscovered. In the last few years legislators have shown some willingness to address the problems of nanobiotechnology risk regulation specifically, but this process is still at the development stage. Meanwhile, public "nanobio-awareness", hence, reception of this technology has not changed significantly over the last decade. Overall, education and further research are deemed to be the best instruments to help shape an adequate public and regulatory approach.