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## THE APPLICATION OF A RESPONSIBLE APPROACH TO NANORESEARCH

**Summary.** The paper is focused on the definition of the responsible approach of a scientist specialized in nanotechnology research and points out different understandings of responsibility. It also determines the fundamental risks the scientist may deal with in their profession and interprets the main legislative frameworks applicable for Europe. In the conclusion the paper emphasises the necessity of determining the certain conditions for responsible research in nanosciences and the more effective use of the precautionary principle.

**Keywords:** applied ethics, nanotechnology, risks, nanoethics, responsibility.

## STOSOWANIE ODPOWIEDZIALNEGO PODEJŚCIA W ZAKRESIE BADAŃ NANOTECHNOLOGICZNYCH

**Streszczenie.** W artykule skupiamy naszą uwagę na definiowaniu odpowiedzialnego podejścia pracownika naukowego, który się kształci, aby być specjalistą w zakresie nanotechnologii, wskazując przy tym na różne możliwości rozumienia pojęcia odpowiedzialności. Jednocześnie wyznaczamy podstawowe ryzyko, z którym naukowiec może się spotkać w swojej pracy oraz interpretujemy główne prawne zasady obowiązujące na obszarze Europy. W zakończeniu naszego artykułu uwypuklamy potrzebę bardziej szczegółowego wyznaczenia niektórych warunków odpowiedzialnego badania w dziedzinie nanotechnologii oraz bardziej efektywnego użycia zasady zachowania ostrożności.

**Słowa kluczowe:** etyka stosowana, nanotechnologia, ryzyko, nanoetyka, odpowiedzialność.

## 1. The shift from the general to individual nanoresearch responsibility

Today nanotechnologies represent one of the key disciplines not only for current but also future human innovations. At the same time, questions arise as to how to ensure that progress not be negative for humans. According to Tondl, current discussions about the direction of technology, primarily about converging technologies, enhancement and risks in the spheres of “possible universes” include also reflections about the necessity of ethics, ethical values, conscience and especially about individual and general responsibility, including responsibility for future generations.<sup>1</sup>

Responsibility is the key concept for the work of scientists focusing their attention on the safe progress of nanoscience research. When taking into consideration particular ethical problems a scientist may face in this relatively new discipline, the questions about the way of applying responsibility and also about the clear definition of responsible behaviour arises. Nanoresearch represents the possibilities scientists so far have dealt with only to a limited extent. The increase of opportunities such as intervention on the human body for non-medical procedures opens the important discussion about the responsible approach of individual participants who are “Member States, employers, research funders, researchers and more generally all individuals and civil society organisations interested or involved in nanosciences and nanotechnologies (N&N) research.”<sup>2</sup> Although several parties play important role in this process, the presented paper is focused particularly on the responsibility in connection with scientists who prepare new utilisation opportunities for nanotechnologies in practice mainly in laboratories and specialised institutes. The stated definition is important mainly because the “collective responsibility at the level of innovation systems should somehow be translated to the individual responsibilities of all the participants involved (scientists, industrialists, policy makers etc).”<sup>3</sup>

The shift from general to individual responsibility foresees the specification of the following points in more detail. The responsible approach to innovations should be termed and specified in connection with the activity of individual participants involved in nanoresearch. The approach includes:

1. “The deliberate focus of research and the innovation products to achieve a social or environmental benefit.

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<sup>1</sup> Tondl L.: Hodnoty, komunikácia, múdrosť. Výber vedeckých prác Ladislav aTondla pre aplikovanú etiku. Belianum, BanskáBystrica 2014, pp.292.

<sup>2</sup> K(2008) 424:2008: Commission recommendation on A code of conduct for responsible nanosciences and nanotechnologies research adopted on 7<sup>th</sup> February 2008.

<sup>3</sup> Malsch I. et al.: Communicating Nanoethics. Annual Report 4 on Ethical and Societal Aspects: research report. ObservatoryNano, Glasgow 2012. pp.66.

2. The consistent, ongoing involvement of society, from beginning to end of the innovation process, including public & non-governmental groups, who are themselves mindful of the public good.
3. Assessing and effectively prioritising social, ethical and environmental impacts, risks and opportunities, both now and in the future, alongside the technical and commercial.
4. Where oversight mechanisms are better able to anticipate and manage problems as well as opportunities and which are also able to adapt and respond quickly to changing knowledge and circumstances.
5. Where openness and transparency are an integral component of the research and innovation process.”<sup>4</sup>

## **2. Issues connected with the application of the general responsibility**

The ambivalence of the particular implications of nanotechnologies is the significant reason why it is important to determine the responsible approach of a nanoscience scientist. “Nanotechnologies are enabling technologies, with a high potential benefits for consumers, workers, patients and the environment, as well as the creation of jobs. On the other hand, nanotechnologies and nanomaterials may expose humans and the environment to new risks, possibly involving quite different mechanisms of interference with the physiology of human and environmental species.”<sup>5</sup> If we want to minimise these new threats, today we cannot choose the procedure based on the ban on the use of nanoparticles we do not have detailed toxicological information about. The solution lies in the creation of particular conditions for nanoresearch. From the point of view of scientific ethics, these conditions should include mainly the requirements of a scientist’s individual responsibility and determination of behaviour required for stated discipline, since scientists are often first to face the moral dilemmas connected with the use of nanotechnologies.

The European Union documents regulating the approach to nanotechnologies contain recommendations pointing rather to the producers’ responsibility in general: “nanomaterials should be covered in a multi-faceted, differentiated and adaptive body of law based on the precautionary principle, the principle of producer responsibility and ‘the polluter-pays’ principle.”<sup>6</sup> However, the stated approach represents only general recommendations and ignores the fact that the responsibility of particular participants in the production process of

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<sup>4</sup> Sutcliffe H.: A report on Responsible Research & Innovation: research report. 2011, pp. 34.

<sup>5</sup> COM(2008) 366 final: Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. Regulatory Aspects of Nanomaterials : research report. Commission of the European Communities, Brussels 2008, pp.11.

<sup>6</sup> P6\_TA(2009)0328 : Regulatory aspects of nanomaterials. European Parliament resolution of 24 April 2009 on the regulatory aspects of nanomaterials (2008/2208(INI)).

the new technology is different. By determining the special conditions of the responsible approach it is possible to prevent such situations for manufacturers to have the opportunity to place a potentially harmful product on the market without previous ethical reviews in the research period. Since the European Parliament “calls for the application of a ‘duty of care’ for manufacturers that wish to place nanomaterials onto the market and calls on them to adhere to the European Code of Conduct for Responsible Nanosciences and Nanotechnologies Research”<sup>7</sup>, an equal emphasis should be placed on all parties involved. Otherwise, generalisations may occur and also the inaccurate specification of the responsibilities of participants in different phases of nanoparticle preparation. It is important to emphasise that a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research is addressed also to scientists themselves. On the other hand, they are perceived only as a component of stakeholders involved in nanosciences and nanotechnologies, and ethically there is no special emphasis placed on their working process.

Today, the mentioned Code of Conduct for Responsible Nanosciences and Nanotechnologies Research applies to nanoscience researchers; their work, however, is not regulated by any detailed recommendations. The countries that have established more detailed requirements for safe and responsible research in the stated discipline are exceptions. In the Slovak Republic there are no procedures solely governing the ethical aspects of nanotechnological research. In the following table these phenomenon are depicted without completeness.

Table 1

Summary of documents governing the responsible approach in nanotechnology research, which are applicable in the European Union and the Slovak Republic.

| Generally applicable documents of the European Union governing the responsible approach in research | Year | Note  |
|---|------|---|
| Charter of Fundamental Rights of the European Union <sup>8</sup>                                    | 2000 | Declaration of the European Union’s fundamental values: dignity, freedom, equality and solidarity |
| European Textbook on Ethics in Research <sup>9</sup>  | 2010 | Definition of the ethical aspects of the research   |
| Ethical and Regulatory Challenges to science and research Policy at the global level <sup>10</sup>  | 2012 | Specifying the European values for the responsible research and approach to innovations           |

<sup>7</sup> P6\_TA(2009)0328 : Regulatory aspects of nanomaterials. European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)).

<sup>8</sup> (2000/C 364/01) : Charter of Fundamental Rights of the European Union. Formal declaration of European Parliament, Council and Commission of 7 December 2000.

<sup>9</sup> Lino P.: European Textbook on Ethics in Research. [online]. Publications Office of the European Union, Luxembourg 2010, 212 p. [cit. 2016-05-23]. Dostupné na internete: <[https://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/textbook-on-ethics-report\\_en.pdf](https://ec.europa.eu/research/science-society/document_library/pdf_06/textbook-on-ethics-report_en.pdf)>.

| European documents governing the responsible nanosciences and nanotechnologies research   | Year | Note  |
|---|------|---|
| The communication of the Commission Towards a European Strategy for Nanotechnologies <sup>11</sup>  | 2004 | The emphasis on the importance of competitiveness in the European Community and ensuring the responsible development in the stated discipline |
| Nanosciences and nanotechnologies: Action plan for Europe 2005-2009 <sup>12</sup>   | 2005 | Focus on safe and responsible nanotechnologies research   |
| Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies <sup>13</sup> | 2006 | Adjustment of toxicological criteria for nanomaterials  |
| Opinion on the Ethical Aspects of Nanomedicine <sup>14</sup>  | 2007 | Definition of fundamental ethical issues on the nanomedicine development and recommendations for the safe use of innovations.                 |
| The communication of the Commission "Regulatory aspects of nanomaterials" <sup>15</sup>   | 2008 | Adjustment of conditions for the use of safe nanomaterials.   |
| The Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research <sup>16</sup>   | 2008 | A voluntary code supporting an integrated, safe and responsible approach.   |
| Action Plan Nanotechnology 2015 <sup>17</sup>   | 2011 | The emphasis on the cooperation and determination of the priority areas of interest.  |

<sup>10</sup> European Commission: 2012. Ethical and Regulatory Challenges to Science and Research Policy at the Global Level. [online]. Publications Office of the European Union, Luxembourg 2012. 60 p. [cit. 2016-05-23]. Dostupné na internete: <[http://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/ethical-and-regulatory-challenges-042012\\_en.pdf](http://ec.europa.eu/research/science-society/document_library/pdf_06/ethical-and-regulatory-challenges-042012_en.pdf)>.

<sup>11</sup> COM(2004) 338 final: Oznámenie komisie smerom k európskej stratégii pre nanotechnológie: výskumná správa. Commission of the European Communities, Brusel 2004, 27 pages.

<sup>12</sup> European Commission: Nanowissenschaften und Nanotechnologien: Aktionsplan für Europa 2005-2009. [online]. Publications Office of the European Union, Luxembourg 2005. 16 p. [cit. 2016-05-23]. Dostupné na internete:

<[https://ec.europa.eu/research/industrial\\_technologies/pdf/policy/action\\_plan\\_brochure\\_de.pdf](https://ec.europa.eu/research/industrial_technologies/pdf/policy/action_plan_brochure_de.pdf)>.

<sup>13</sup> European Commission: Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies. [online]. SCENIHR, Brusel 2006, 79 p. [cit. 2016-05-23]. Dostupné na internete:

<[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_003b.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_003b.pdf)>.

<sup>14</sup> Hermerén G. et al.: Opinion on the ethical aspects of nanomedicine - Opinion N° 21. [online]. EGE, Brussels 2007, 123 p. [cit. 2014-02-07]. Dostupné na internete:

<[http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion\\_21\\_nano\\_en.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_21_nano_en.pdf)>.

<sup>15</sup> P6\_TA(2009)0328: Regulačné aspekty nanomateriálov. Uznesenie Európskeho parlamentu z 24. apríla 2009 o regulačných aspektoch nanomateriálov (2008/2208(INI)).

<sup>16</sup> K(2008) 424:2008: Odporúčanie komisie zo 7. februára 2008 o kódexe správania pre zodpovedný výskum v oblasti nanovied a nanotechnológií.

<sup>17</sup> Schavan A.: Action Plan Nanotechnology 2015. Bonifatius GmbH, Paderborn 2011, 62 s.

| Slovak documents governing the approach to the responsible research   | Year | Note   |
|---|------|--|
| Recommendation of the Slovak Research and Development Agency Council, Correct scientific practise <sup>18</sup> | 2004 | General principles for researchers often referring to international standards  |
| Ethical Code of Slovak Academy of Science <sup>19</sup>   | 2015 | Document governing the behaviour of the employees of Slovak Academy of Science |

Source: Own

The emphasis of European institutions on nanoethics can be seen particularly in the increasing of competitiveness for member countries in the nanoindustry. Today nanotechnology is the key for other investments and the economic growth of individual states. “National capacities are often inadequate for the creation of world-class poles of excellence. It is therefore urgent that these programmes are coordinated in a way that effort is consolidated and focussed so as to ensure a critical mass and greater impact within the ERA on the three key synergetic axes: research, infrastructure and education.”<sup>20</sup> Therefore, the European Union rejects the declaration of an absolute moratorium on nanotechnology innovations, while stressing that one of the possible impacts is “the establishment of ‘technological paradises’, i.e. when research is carried out in zones without regulatory frameworks and is open to possible misuse. Our consequent inability to follow developments and intervene under such circumstances could lead to even worse consequences. The Precautionary principle, as used up to now, could be applied in the event that realistic and serious risks are identified.”<sup>21</sup> When applied consistently, the mentioned Precautionary principle may lead to unjustified moratoria: “As long as risk assessment studies on long-term safety is not available, research involving the deliberate intrusion of nano-objects into the human body, their intrusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment should be avoided.”<sup>22</sup> On the other hand, there is the much more serious disadvantage of this principle, which can be characterized by the following points like:

- “proportional to the chosen level of protection,
- non-discriminatory in their application,
- consistent with similar measures already taken,

<sup>18</sup> Ftáčniková S.: Správna vedecká prax. Odporúčanie rady APVT. APVT. Bratislava 2004, 32 s.

<sup>19</sup> Pastorek J.: Etický kódex SAV. SAV, Bratislava 2015, 4 s.

<sup>20</sup> KOM(2004) 338 final: Communication from the Commission. Towards a European Strategy for Nanotechnology : research report. Commission of the European Communities, Brussels 2004, pp.27.

<sup>21</sup> KOM(2004) 338 final: Communication from the Commission. Towards a European Strategy for Nanotechnology : research report. Commission of the European Communities, Brussels 2004, pp.27.

<sup>22</sup> K(2008) 424:2008 : Commission recommendation on A code of conduct for responsible nanosciences and nanotechnologies research adopted on 7<sup>th</sup> February 2008.

- based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- subject to review, in the light of new scientific data, and
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive assessment.”<sup>23</sup>

The effort to eliminate the production of such innovations which can cause any risk (including an unpredictable risk) connects the individual characteristics of the Precautionary principle. However such understanding causes several problems. One of them is only the theoretic applicability of the principle. “The precautionary principle is not—and cannot properly claim to be—a complete decision rule at all. Instead, it provides a general normative guide to the effect that policy-making under uncertainty, ambiguity and ignorance should give the benefit of the doubt to the protection of human health and the environment, rather than competing organizational or economic interests.”<sup>24</sup> When assessing a risk we cannot rely on abstract decision-making models, but it is necessary to elaborate a system of specific recommendations that would correspond to real examples from practise. According to Belyaletdinov the necessity of mass regulation of ethical issues arising with nanotechnologies development as well as seeking moderate and therefore also more numerous ways of their definition manifested in the idea of “the responsible approach” and “the stable development” of nanotechnologies. These ideas are represented in the sphere of “soft law” – recommended documents that determine the direction of the technology development.<sup>25</sup>

### 3. The application of a responsible approach in the nanoresearch

In this context, it is important to draw attention to the possibilities that can realize the “idea of a responsible approach”. The specification of ethical principles for individual professions involved in nanotechnologies is an important factor for their successful implementation. For a scientist’s work it means drawing up the specific conditions for responsible nanoscience research based on the knowledge of mainly professional ethics (ethics of scientists and researchers), but also bioethics as well as business and organisational ethics.

Considering the characterisation of a scientist’s responsible behaviour, the current stylization of the Code of Conduct for the Responsible Nanoscience and Nanotechnologies

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<sup>23</sup> COM(2000) 1:2000 : Communication from the commission on the precautionary principle.

<sup>24</sup> Stirling A.: Risk, precaution and science: towards a more constructive policy debate. In EmboPress. /online/. 2007, [cit. 2016-04-27]. Available on:<http://embor.embopress.org/content/8/4/309.full#ref-15>.

<sup>25</sup> Belyaletdinov R.R.: Риск как элемент этики новых технологий в области биомедицины. /online/. 2011. 14 p. [cit. 2016-04-27]. Available on:[http://iph.ras.ru/uplfile/root/biblio/bioeth/bioeth\\_5/4.pdf](http://iph.ras.ru/uplfile/root/biblio/bioeth/bioeth_5/4.pdf).

Research is apt only generally, however in order for better integration into scientists' working habits it can be extended by more specific aspects or recommendations regarding procedures in some ethically problematic situations (i.e. how to proceed with technologies when we cannot estimate the risk rate of a negative impact in the future and so on.).

We can also characterise the fundamental spheres of responsibility of the nanoscience scientist. It is mainly self-responsibility (i.e. ensuring adequate protection against the harmful effect of nanoparticles), responsibility to consumers (i.e. elimination of the production of such products with predominant negative effects on human life and health) and last but not least responsibility to the environment (to prefer mainly solutions that are not burden on the environment). It is necessary to determine specific procedures in order to facilitate the implementation of a responsible approach. It involves the clear delegation of responsibilities not only within a profession but also within entire institutions. It is appropriate for such solutions in nanoethicsto come under so called systemic solutions, when besides detailed ethical recommendations for a scientist, procedures including prevention methods and solutions within entire organisations are also developed.

The realization of some components of the ethic programme (i.e. establishment of the ethics committee and ethical code for a given type of institution and training activities) should be part of organisational ethics. Glasa states that the building of a necessary "ethical culture" within a team, a regular debate on the subjects of a research and scientific ethics and following the example of senior researchers and "scientific authorities" is very important.<sup>26</sup> According to Fobel it is also possible to focus on "pro-ethical employees' socialisation", clarifying appropriate behaviour, creating an environment for ethical dialogue, the appreciation of moral behaviour and the public condemnation of unethical behaviour, the incorporation of ethical requirements into staff policy and so on.<sup>27</sup>

For the support of a responsible approach in the nanosciences and nanotechnologies it is important not only to refine individual scientists' ethical values, but also to effectively eliminate unethical practises. The application of effective sanctions and seemingly elementary rules is also related to it. According to Glasa it is inevitable to weaken/solve factors causing excessive pressure on a scientist and predispose them to the development of unethical action and behaviour (i.e. time and financial stress, overestimating "positive" research results, policy of granting agencies, excessive pressure on the number of publications and so on.)<sup>28</sup>

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<sup>26</sup> Glasa J.: Etické komisie a biomedicínsky výskum. Vybrané etické a inštitucionálne aspekty : doctoral dissertation. Masarykova Univerzita, Brno 2006, pp.89.

<sup>27</sup> Fobel P.: Nástroje riadenia akademickej etiky. In Akademickáetika. Tvorba a implementácia etického kódexu. Univerzita Mateja Bela, Banská Bystrica:2011, pp. 37-64.

<sup>28</sup> Glasa J.: Etické komisie a biomedicínsky výskum. Vybrané etické a inštitucionálne aspekty: doctoral dissertation. Masarykova Univerzita, Brno 2006, pp.89.



## 4. Conclusion

The present paper points to the need of the establishing of a functional ethical frame clearly defining the responsibility requirement of a scientific research worker in nanoscience and nanotechnology. The research in the field of nanoscience and nanotechnology includes research activities from basic to applied research, technological developments as well as preparation and co-research supporting scientific advice, rules and regulations.<sup>29</sup> The need to set specific moral rights and obligations is based on the current boosting of innovation. This ambition should cover the following points:

- “elucidating what constitutes justice, human flourishing and sustainability;
- identifying opportunities for nanotechnology to accomplish the goal and anticipating impediments to its doing so;
- developing standards for assessing prospective nanotechnologies;
- providing ethical capacity (i.e. tools and resources that assist individuals and organizations to make ethically informed decisions) to enable society to adapt effectively to emerging nanotechnologies; and
- identifying limits on how the goal ought to be pursued.”<sup>30</sup>

According to Glasa, the application of these methods may lead to the elimination of tragedies caused by the irresponsible usage of new technologies. It would appear these tragedies are the consequences of mainly the scientific and professional misconducts but the investigation of such disasters very often reveals shortcomings in the scientific methodology and also violations of the vocational ethics of competent researchers, infringement of rules and shortcomings in ensuring the process and monitoring of clinical trials or studies.<sup>31</sup>

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<sup>29</sup> K(2008) 424:2008 : Commission recommendation on A code of conduct for responsible nanosciences and nanotechnologies research adopted on 7<sup>th</sup> February 2008.

<sup>30</sup> Sandler R.: Nanotechnology: The Social and Ethical Issues. Washington: Woodrow Wilson International Center for Scholars, 2009, pp.62.

<sup>31</sup> Glasa J.: Etické komisie a biomedicínsky výskum. Vybrané etické a inštitucionálne aspekty: doctoral dissertation. Masarykova Univerzita, Brno 2006, pp.89.

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## Omówienie

Nanotechnologie to szybko rozwijający się kierunek, który tworzy bardzo dużo innowacji, często już użytkowanych w praktyce. Jednocześnie ten rozwój przynosi wiele pytań z zakresu etyki. Aby znaleźć odpowiedź na te pytania, należy przede wszystkim wyznaczyć zakres odpowiedzialności pojedynczych badaczy, którzy są w najbliższym kontakcie z tym jakże ryzykownym działem nauki. W artykule określiliśmy odpowiedzialne podejście pracownika naukowego, który się kształci, aby być specjalistą w zakresie nanotechnologii, wskazując przy tym na różne możliwości rozumienia pojęcia odpowiedzialności. Uwypuklamy potrzebę bardziej szczegółowego wyznaczenia niektórych warunków odpowiedzialnego badania w dziedzinie nanotechnologii oraz bardziej efektywnego użycia zasady zachowania ostrożności.