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VARIA – ETHICS

Dealing with Scientific Integrity Issues: the Spanish Experience

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Abstract Integrity has been an important matter of concern for the scientific community as it affects the basis of its activities. Most countries having a significant scientific activity have dealt with this problem by different means, including drafting specific legal or soft law regulations and the appointment of stable or ad hoc committees that take care of these questions. This has also been the case in Spain. After the period of transition between dictatorship to a democratic regime, and, particularly, after the entrance in the European Union, scientific activity has increased in the country. As it could be expected, problems of misconduct have appeared and different institutions have been dealing with these matters. One of the best examples is that of Consejo Superior de Investigaciones Cientificas (CSIC), the largest institution devoted to scientific research belonging to the Spanish Government. The experience of the CSIC's Ethics Committee in dealing with conflicts related to scientific practices is discussed here.

Keywords Integrity · Ethics · Ethics committee

Introduction: Scientific Misconduct

The understanding of the world we live in has been an essential ambition of the human mind. Since we have a written record of philosophical activity, we know that theories that try to comprehend universe, matter and living organisms have been formulated. In a long historical process, and more specifically during the last two centuries, science has become a powerful intellectual activity that has allowed reaching unprecedented levels of knowledge. Scientific practice is at present being developed within the framework of well-established rules that, although they may vary between disciplines, are intended to ensure that the results have been obtained with an acceptable level of credibility. This may be the main reason why deviations from established scientific practices are considered a major fault in professional behavior by scientists.

At the same time, the technological applications that result from science may often have a significant impact upon the life of citizens at different levels. Our society is presently based on high levels of technology, including medical, that allow the life of a majority of humans reaching unprecedented levels of welfare. While the public in general are aware of this fact, many people are also concerned about the way some of these applications affect their own life. Different types of approaches have been attempted by different institutions with the aim of employing technologies in a way that make them acceptable to the majority of society. This procedure is aimed toward avoiding conflicts that have often occurred when citizens suddenly face applications that alter aspects of their everyday life. Ethics committees are one of such advisory systems that have been employed, with limited success, to introduce philosophical, juridical and anthropological considerations, as well as the best possible level of scientific information, in the process of deciding how new technologies are applied.

From another point of view, the way how science is applied in practice may also produce reactions in citizens that might not agree with these activities, or they may feel threatened by some of the things scientists do. This feeling has been widely exploited by science fiction literature and

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movies. It might have started with the applications of nuclear physics or chemistry. The accidents that occurred in some cases and the military applications that have been developed during the twentieth century have created a threatening image of science. Nevertheless, at present it is essentially the way life sciences research is carried out with humans, animals or systems that may have an impact on the environment that concerns a significant number of citizens. As a consequence, society has reacted in such a way that at present scientists carry out their work within a framework that has become the object of an increasing number of laws and rules. The use of human individuals or samples from humans has been the object of specific legislation in most of the countries since the Nurnberg trial, the use of animals in experimentation is the object of very specific rules, and experiments with genetically modified organisms, and in general biosafety, has been the object of legislation in many countries. At the same time, research in public institutions uses public funds that have specific rules of spending and they may be complex. But besides all these legal requirements, science has its own set of working rules that have been made explicit in many countries.

The methodological rules that science follows have been developed implicitly during centuries and the flourishing of philosophy of science during the twentieth century has made explicit the basis of these rules. To define a basic method for the practice of science might need a basic assumption that scientists follow a common method of carrying out their work. In fact, a large variation in methodologies exists in particular between disciplines. But, regardless of the discipline that the scientist is working on, at some point a professional of science may act by breaching a rule that might be important from a methodological point of view and that would therefore undermine the value of the results obtained. In this case, it is considered that this professional has undergone scientific misconduct. Cases of scientists who may have pushed the limit of scientific practices beyond what it is considered acceptable have been discussed for centuries, but the importance of science in our time, the number of professionals and the competitivity that has been developing in many countries have put this question in the forefront of scientific discussion. The most common cases of scientific fraud are fabrication and falsification of data and plagiarism. However other types of misconduct arise, for instance in the authorship rules in publications or in the relation between supervisors and supervised, subjects that produce a large number of frequent conflicts within the scientific community.

Probably, one of the best known examples of institutions designed to deal with these cases is the Office for Research Integrity of the USA. It was created in 1989 as an Office of Scientific Integrity after a number of cases of alleged misconduct in biomedical research were discussed in the American Congress. It is now an office within the Department of Health of the United States and deals with conflicts that may eventually appear in relation to grants funded by this department. Every year, the office publishes case summaries in its web page (http://ori.dhhs.gov/case_summary) that may eventually lead to penal action toward scientists for breaching American federal legislation. In Europe, ethics committees were established in different countries during the 1990s, but the Nordic countries and Denmark in particular, where committees on Scientific Dishonesty were established since 1999, had greater experience in dealing with these matters. The European Science Foundation (2000, 2008) did an interesting job of exchanging information between European countries and produced a number of reports on these issues. In the same direction ALLEA, the European Federation of Academies, has worked on research integrity producing a number of documents that serve as guidance in writing codes of Good Scientific Practices in Europe (ALLEA 2010). In spite of all these actions, it has been reported that article retractions have increased (Steen et al. 2013), although this might be a consequence of the increasing awareness of the question.

The Case of Spain

Spanish science has had a significant social development during the last 40 years, coinciding with the establishment of a democratic regime and with the increase in political, cultural and economic activity in the country. The scientific tradition was essentially broken during the Spanish Civil War (1936–1939) and, although the Spanish Research Council (Consejo Superior de Investigaciones Cientificas: CSIC) was founded in 1939, the dictatorial regime that resulted from the war did little to allow the development of a scientific activity equivalent to that existing in international science. In this sense, it can be said that the Spanish scientific community is young and that the main features of its activity have been built in the recent 40 years. This is especially true for the structures that manage science funding and evaluation. A key step in this sense was the approval in 1985 of the first Law on Science (the Law for Support and Coordination of Science) that formulates a model for the organization of the research system in Spain. It included a National Plan for Research that incorporates a fund managed through a system of grants and an agency (Agencia Nacional de Evaluacion y Prospectiva) that takes care of scientific evaluation of grant proposals. The establishment of the National Plan was also the opportunity for an important increase in funding for science. The system was in place while the public funds were rising steadily with important increases between 2005 and 2009. A new

law (Law for Science, Technology and Innovation) was approved in 2011 that included the creation of a new agency for the management of grants. The economic crisis that appeared since 2009 produced a significant drop in science funding and the paralysis of the reforms that were proposed in the new law.

Another important landmark for the opening of Spanish science occurred in 1986 when Spain joined the European communities. Belonging to European communities meant for Spanish science on the one hand that research groups could be included in European projects, thus generating a new opportunity no only for funding of science, but also for creating new contacts with the European scientific community. On the other hand, European legislation had to be transposed to Spanish Law and that included regulations dealing with scientific activity. The fact is that, for a number of reasons that have already been outlined, Spanish science had an important increase in activity from 1985 to 2009. At the same time Spanish research groups became aware of the fact that they had to comply with international standards regarding general scientific practices. A number of changes were introduced into the laws and they had an important influence in the way science was applied in laboratories and in relation to the international scientific community. In this way, the experience of Spain may be of interest to other countries in similar situations when science is developed toward reaching international standards.

One of the main achievements that Spanish research groups and institutions accomplished during this transition period has been to comply with regulations that organize scientific activity in question, such as the use of human samples, experiments with animals or genetically modified organisms. Spain has transposed to its legislation the main European directives and, accordingly, universities, research institutes and hospitals had to introduce the rules and practices that were required. In fact, the Spanish Constitution of 1978 already recognized the basic rights guiding research with humans and human samples. Starting in 1986, a number of specific laws were approved, as well as changes in the Spanish Penal Code, which regulate these activities. These laws include, for instance, a regulation of clinical trials and procedures for the approval of new protocols for treatments in hospitals. More recently, a Law for Biomedical Research was approved in 2007 that integrates in a single text and updates all these norms. The appointment of a Spanish Committee for Bioethics was also included. During this time, Spain has ratified international conventions related to bioethics, including the Oviedo Convention. Bioethics committees have been established in the main Spanish hospitals and take care of matters regarding clinical practices according to these norms.

Regulations on experiments with animals have been implemented since 1988 according to European directives and the own development of Spanish legislation. Animal experimentation committees have been put into operation in universities and research institutes, and animal houses have been built or reformed according to European and international rules. With the development of recombinant techniques in laboratories and the use of genetically modified plants and animals, a specific regulation on biosafety was developed and applied essentially after the transposition of the 1990 European Directive on deliberate release in the environment of genetically modified organisms. A National Commission on Biosafety was established in 1998 within the Ministry of the Environment (presently, Ministry of Agriculture, Food and Environment). It has acted as the competent authority for this matter approving biosafety facilities and monitoring field experiments. In 2013 it celebrated its 100 meetings and reported more than 200 inspections of equipment and more than 500 field experiments. In general terms, it can be said that in Spain the regulations concerning research related to humans, animals and genetic modifications are in place and follow European standards. Scientists are in general aware of these rules and institutions have generated the appropriate means to allow research activity to be carried out following the regulations that apply to their work.

Another change that has occurred in the structure of Spanish science has been an increasing awareness that good practices are an essential element of scientific activity. It is possible that in the past this was not an important question in Spain for two practical reasons. The first one is that the quantity and general quality of the science that was produced at that time in Spain was low and therefore scientists did not experience the requirement to publish in high impact journals. A collateral effect would be that the reproducibility of the results published was rarely checked. A second reason might be that the funds to carry out research in Spain were not very high, but the scientific community was small and the competition moderate. It was normal that 60 % of the projects presented in the calls of the National Plan were funded. From the point of view of employment, most of Spanish scientists were working for the public sector, including universities, and therefore followed the rules of public civil service, in particular in their salaries. In this situation, the impact of research only had a major influence on the salaries of scientists when they applied for promotion at different scales. However, a system for rewarding scientific productivity was approved in 1989 that introduced an increase in the salary of university professors and later of public scientists after an external evaluation, if they could prove that they participated in research activities. Although the standards of quality are moderate, the number of publications in

international journals is one of the requirements for the salary increase. The culture of evaluation of scientific productivity was introduced also in hospitals, thus creating a demand for publication in the different areas of activity related to research.

Therefore, with the increase in the quantity and the quality of the research being developed in Spain, methods to evaluate the impact of the scientific activity were introduced that were important not only to have access to research funds, but also, as described above, to increase the personal salary of university professors, clinicians and professional scientists. Many people thought that was a progress in relation to the previous system when no evaluation whatsoever was carried out and when the salaries of all scientists were the same whatever the quality of the work that they were doing. However, the prediction by some of us was that sooner or later problems of scientific integrity would appear in Spanish science. Therefore, some institutions started to build up their own system to promote good scientific practices and to develop some means to react if cases of misconduct arise. Probably, the first Code of Good Scientific Practices in Spain was that of the Municipal Institute of Medical Research in Barcelona that has been the base of the present Code of Good Research Practices of the Barcelona Biomedical Research Park (Parc de Recerca Biomedica de Barcelona 2007). Another good example is that of the Spanish Research Council (CSIC) that will be described below. The Spanish Bioethics Committee (2011) has also published guidance on Codes of Good Scientific Practices.

The Ethics Committee of Consejo Superior de Investigaciones Cientificas (CSIC)

The Ethics Committee of the Spanish Research Council was established following a reform in the statutes of CSIC in 2007. CSIC had already the experience of a Bioethics Commission that was in charge with questions related to compliance with the regulation of work using human samples, animals and GMOs. This commission had the task of making a revision of the ethical aspects of the projects presented by CSIC scientists and to give advice to research groups and CSIC institutes on how to revise their facilities and procedures to work in accordance with existing regulations. The Ethics Committee was formed by senior members from different scientific areas and included members with juridical and philosophical training. It has two subcommittees, the Bioethics Subcommittee that has the functions of the previous Bioethics Commission, and whose chairman is a member of the Ethics Committee, and a Conflicts Subcommittee that deals with conflicts that involve CSIC staff in relation with good scientific practices.

The first task of the CSIC Ethics Committee was to draft a Code of Good Scientific Practices that was approved by the Board of CSIC in 2010 (Comite de Etica. Consejo Superior de Investigaciones Cientificas 2010). The Code of Good Scientific Practices follows the models used in other countries. In particular, the information collected by the European Science Foundation (2008) and ALLEA (2010) was consulted as well as similar regulations existing in countries such as Germany (Max-Planck Society) or Finland (Academy of Finland). The texts were adapted to the structure of CSIC as a multidisciplinary public institution formed by permanent scientists and technicians and a large number of students and postdocs. The code is divided into four chapters and an annex that contains a list of the main legislation existing in Spain related to scientific activity. The four chapters are devoted to:

1. *The principles of work in research* includes a description of the general methods employed in scientific research as well as experiment design, management of data and care in the use of funds in research;
2. *The researcher as a science professional*, in particular relations between scientists, conditions for evaluation and curriculum presentation as well as conflicts of interest and intellectual property protection;
3. *Scientific publications*, where emphasis is given to authorship and recognition of previous authors;
4. *The Institutional Framework* that includes the duty of informing on research conditions, promotion and non-discrimination within the institution.

In the different chapters, the code tries to prescribe the general principles that scientific activity normally follows to achieve its goals. It was intended to make explicit the ways how scientists behave, such that young students arriving at CSIC may find guidance on how to carry out their work. It has also served the Ethics Committee as a reference when specific conflicts have been presented to its attention.

From its constitution, the CSIC's Ethics Committee had the pressing need to deal with a number of conflicts that were related with the main patterns of scientific misconduct: fabrication, falsification and plagiarism of scientific results, as well as questions related to authorship, relations among scientists and between supervisors and students, conflicts of interest, etc. The committee drafted its Internal Rules of Procedure to deal with these conflicts that were approved by the board of CSIC. They included as a first step the need to consider whether the committee was competent with the matter drawn to its attention. In fact, conflicts dealing with good practices often overlap with legal, labor or safety matters. The rules also include the actions and deadlines that had to be followed in each case. In this way, the Committee assumed for the first time in

CSIC a role of mediation in different types of conflicts involving its staff. The procedures approved included the possibility to appoint specific members who were taking care of getting information of each case, in particular when interviewing individuals involved in different conflicts or an ad hoc external committee when an analysis of a specific scientific question was needed. In this way the CSIC's Ethics Committee underwent at the same time a task of writing opinions dealing with ethical behavior of CSIC staff, such as a Code of Good Scientific Practices, a task of supervising the work of Bioethics Subcommittee and a task of dealing with conflicts when CSIC scientists were involved.

The CSIC's Ethics Committee dealt during its first 4 years with a number of conflicts including disputes on authorship, use of funds and access to instruments, and supervision of students. It has analyzed two cases of plagiarism and a complex case of conflict of interests between a research group and a spin-off company. The committee has an advisory role to the President of CSIC and, in accordance to this statute, its work and conclusions are confidential except in those aspects that are communicated to the people concerned and that may include scientific journals in the case of conflicts involving publications. However, in two difficult cases the news appeared in the public media. One of these cases was an article published in Science by authors from different countries and expertises and including CSIC scientists (Beloqui et al. 2009). After the appointment of an ad hoc committee and discussion with the different institutions involved, the CSIC Ethics Committee recommended the retraction of the article that was agreed by the authors and the journal (Beloqui et al. 2010). In another case, some authors raised concerns about the results produced by CSIC scientists in a number of different articles. After a similar procedure, the Ethics Committee recommended corrections or retractions in a number of articles. At least ten of these articles have been retracted from international journals publishing articles on environment or general biology (see Retraction Watch 2013). Following the experience in the first of these cases the committee produced an opinion giving advice to CSIC scientists on the behavior to be followed in the case of multi-authors and multidisciplinary articles, where it could be impossible for some of the authors to verify the quality of a fraction of the results presented (Consejo Superior de Investigaciones Cientificas 2011). It was also decided to work on a guidance document in relation to conflicts of interest that were observed in particular when scientists collaborated in the creation of start-up companies. These opinions would have the aim of orienting the work of CSIC scientists in matters that have been found to be the origin of a number of conflicts.

Conclusions

The experience of the Ethics Committee in the Research Council (CSIC) in Spain allows concluding that institutions in countries where scientific activity is in a process of development have to consider questions about scientific integrity very seriously to prevent problems that may eventually arise. It may also be concluded that mechanisms to deal with the different types of conflicts that arise in scientific activity have to exist in the present scientific institutions. It is quite possible that young scientists have to be the focus of a lot of attention regarding scientific good practices. When entering science they have to be aware of the existence of a number of rules that in some cases are the object of specific legislation in the country where science is performed and that in other cases they may be summarized in a specific Code of Conduct. And in all cases the example that supervisors and other senior scientists provide is essential to help young scientists to initiate their careers with the proper attitudes toward science practice. It is, however, impossible that cases of scientific misconduct do not appear in any given country. Experience shows that cases exist in different disciplines and in countries with very different traditions in the scientific world. The existence of independent bodies (ombudspersons, ethics committees, etc.) that are competent with conflicts when they arise is essential to deal with these issues in the legal and cultural framework that exists in each different country. The quality and the independence of the work of these institutions are an essential element that should help to facilitate promoting and maintaining the credibility of the scientific activity that is needed in societies where scientific questions are at the center of their culture and economy.

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