Interested in European research?

*Research*eu is our monthly magazine keeping you in touch with main developments (results, programmes, events, etc.). It is available in English, French, German and Spanish. A free sample copy or free subscription can be obtained from:

European Commission
Directorate-General for Research
Communication Unit
B-1049 Brussels
Fax (32-2) 29-58220
E-mail: research-eu@ec.europa.eu
Internet: http://ec.europa.eu/research/research-eu

EUROPEAN COMMISSION

Directorate-General for Research
Directorate L - Science, economy and society
Unit L.3 - Governance and Ethics
Contact: Jean-François Dechamp
European Commission
Office SDME 7/72
B-1049 Brussels
Fax (32-2) 2984694
E-mail: jean-francois.dechamp@ec.europa.eu
Embedding society in science & technology policy

European and Chinese perspectives

edited by Miltos Ladikas
EUROPE DIRECT is a service to help you find answers to your questions about the European Union

Freephone number [*]:

00 800 6 7 8 9 10 11

[*] Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed

LEGAL NOTICE

Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information.

The views expressed in this publication are the sole responsibility of the author and do not necessarily reflect the views of the European Commission.

A great deal of additional information on the European Union is available on the Internet. It can be accessed through the Europa server (http://europa.eu).

Cataloguing data can be found at the end of this publication.

Luxembourg: Office for Official Publications of the European Communities, 2009

ISSN 1018-5593
doi 10.2777/21028

© European Communities, 2009
Reproduction is authorised provided the source is acknowledged.

Printed in Belgium

PRINTED ON WHITE CHLORINE-FREE PAPER
CONTENTS

Introduction ................................................................. 7
Miltos Ladikas

1. Research ethics: European and Asian perspectives, global challenges ...... 21
Nial Scott

1.1. Introduction ................................................................ 22
1.2. International guidelines on bioethics ........................................ 24
1.3. The tension between bioethics theory and practice ....................... 27
1.4. Ethical approaches and European values ..................................... 30
1.5. The influence of principlism .................................................. 31
1.6. Solidarity and dignity as European values in research ethics ............. 32
1.7. Pluralism in global ethics: is it possible? .................................... 33
References ........................................................................ 36

2. Embedding society in European science and technology policy advice ...... 39
Leonhard Hennen and Miltos Ladikas

2.1. Introduction .................................................................. 40
2.2. History of TA .................................................................. 41
2.2.1. Background: the consequences of technical modernity ............... 41
2.2.2. The institutionalisation of TA ............................................ 43
2.3. Definition, methodology and process of TA. ............................... 46
2.3.1. TA definition .................................................................. 46
2.3.2. TA methods ................................................................... 47
2.3.3. TA process ..................................................................... 49
2.4. TA as bridge builder between science and society ......................... 51
2.5. TA functions .................................................................... 53
2.5.1. Raising knowledge .......................................................... 55
2.5.2. Forming attitudes/opinions ............................................... 56
2.5.3. Initialising action ............................................................. 59
2.6. Conclusions; embedding society in policy ...................................... 62
References ........................................................................ 63
3. Science policy advisory in China: structures and social perspectives .............................. Xinghua Zhu

3.1. Introduction ........................................................................................................ 66

3.2. Current S & T policymaking in China ................................................................ 68
3.2.1. The role of the State Council and its constituent ministries ....................... 68
3.2.2. The State Science and Education Steering Group ......................................... 69
3.2.3. Ministries and agencies of the State Council .................................................. 69
3.2.4. The role of National People’s Congress (NPC) and Chinese People’s Political Consultative Conference (CPPCC) .......................................................... 70

3.3. The limited role of some quasi-governmental institutions as advisory bodies .... 71
3.3.1. Chinese Academy of Sciences (CAS) and Chinese Academy of Engineering (CAE) ........................................................................................................ 71
3.3.2. Chinese Association for Science and Technology ......................................... 72

3.4. The development of science and technology policymaking in China ............... 72
3.4.1. 1985 resolution – all-round reform of science and technology system initiated ........................................................................................................ 73
3.4.2. 1995 resolution – to establish a Chinese-style national innovation system .... 73
3.4.3. 2006 resolution – building an innovation-oriented country/nation ............. 75

3.5. S & T advisory: methodology and societal perspectives: the case of Casted ...... 76
3.5.1. Description: historical evolution of Casted ...................................................... 76
3.5.2. Functions of Casted ......................................................................................... 78
3.5.3. Case illustrations of policy advisory at Casted .............................................. 78

3.6. Summary and discussion: S & T policy mechanisms in China: some suggestions for change ................................................................. 84
Acknowledgements .................................................................................................. 88
References ............................................................................................................... 88

4. Dealing with nanoparticles: a comparison between Chinese and European approaches ................................................................. Michael Decker and Zhenxing Li

4.1. Introduction ........................................................................................................ 92
4.2. Nanotechnology and nanoparticles: an overview of definitions ................. 93
4.3. Nanoparticles: between chances and risks, a global perspective ................. 98

4.4. China’s views on nanoparticles ........................................................................ 101
4.4.1. Precautionary action in Chinese policymaking ............................................ 102
4.4.2. Nanotechnology safety: suggestions for improvement ............................. 105
4.5. European approaches to nanotechnology issues .............................................. 106
4.5.1. Precautionary action in perspective .......................................................... 107
4.5.2. The level of required protection ................................................................. 110
4.6. Concluding remarks .................................................................................... 113
4.6.1. Outlook for China and Europe .................................................................. 116
References .......................................................................................................... 118

Concluding remarks: towards a common approach to science and technology issues ......................................................... 125
Miltos Ladikas

Annex – Author biographical notes .................................................................. 133
ACKNOWLEDGMENTS

The editor and authors would like to thank Jean-François Dechamp, European Commission Directorate-General for Research – Science, Economy and Society Directorate, for his motivation, patience and support for the creation of this book.

We would also like to thank Julie Lucas, University of Central Lancashire, UK, for her very good editing work and accurate suggestions. In work that is produced by non-native speakers such help is invaluable.
Introduction

Miltos Ladikas
This book is the result of a series of discussions initiated by a European Commission-funded project that focused on issues of science and technology (S & T) governance and ethics in Europe and Asia [1]. The initial discussion took place in Ulan Bator, Mongolia, with experts and policymakers from Europe, China and other Asian countries. The specific topics discussed belonged to the overall topic of ‘Science governance and ethics’ in Europe and east Asia and included a range of issues such as the ethics of S & T, technology assessment, science and society programmes and the incorporation of socio-ethical issues in S & T policy. The discussions were highly successful not only in increasing the understanding of the functions and difference in S & T issues between the two regions, but also in producing a series of collaborative initiatives that aim at creating closer ties between the two S & T powerhouses of Europe and China.

European and Chinese S & T are similar in their aims, ambitions and functionality in social development. Europe has declared the era of a ‘knowledge-based society’ in which S & T plays a central role as the means of development and resolution of social problems. China’s view on ‘social development through science’ also gives S & T a main role in the promotion of social welfare and dignified living. Both views place science high up on the policy agenda, not as a panacea for the social problems that the regions are faced with, but perhaps as a result of the realisation that scientific knowledge is a necessary component of every effort to understand the causes of problems and offer sustainable solutions. Scientific knowledge might never take the place of political decision-making but it is making it increasingly effective and coherent.

It is within this thought framework that initiatives on bringing science and society closer together have flourished in Europe and are also taking shape in China. If science is central in solving society’s problems, then it is imperative to promote a healthy symbiotic relationship between the two. Understanding how science works is a means to understand how society can overcome difficulties and vice versa: understanding what society needs is a means to promote the right scientific aims at any given place and time. The complexity underlying this relationship is well reflected in the structure of science in society programmes that we witness in Europe.

---

1 The project’s full title was ‘Ethics in Mongolian and south-east Asian science and technology’, Grant No 0336670, a collaborative effort between the University of Central Lancashire, UK and Unesco Beijing. It was funded by the Ethics and Science Unit, Science, Economy and Society Directorate, European Commission Directorate-General for Research, and run during the year 2007. For details see http://www.uclan.ac.uk/facs/health/ethics/staff/projects/MongolEthics/index.html
European science in society (SiS) programmes

The European Union is a world leader in S & T developments. Both the quantity and quality of its output are on a par with other major economies on the world stage. The EU currently spends about 1.85% of GDP on research and development (R & D), which in monetary terms represents annual expenditure of about EUR 201 billion. There is a wide range of actual expenditure, ranging from below 0.5% to nearly 4% of GDP across EU countries. Moreover, 80% of this expenditure comes from only five countries: Germany, the UK, France, Italy and Spain (Eurostat, 2008).

Europe has adopted an ambitious overall strategy in S & T that aims at making the region the world leader in both output quality and R & D expenditure by 2010 (Treaty of Lisbon, 2007). The specific aim of reaching 3% of GDP on R & D expenditure, two thirds of which should derive from the private sector, is unlikely to be realised in the current economic climate. Nevertheless, Europe has a very well-developed scientific capacity that permeates all levels of socio-economic functions in everyday life. From health and education to energy and transport, S & T developments are an integral part of the life of the average European citizen. The success of S & T in Europe is therefore inextricably related to its proximity to citizens and common understandings of its advantages and risks.

It is within this framework that Europe has developed various SiS programmes at national and international levels. Such programmes represent a relatively new undertaking in the area of S & T in Europe but also in any S & T structure of major world economies. In order to understand the exact function of SiS programmes, it is worth reviewing the three main reasons that lead political authorities to establish them.

• Industrial competitiveness

European industry is highly competitive and technology-intensive. From manufacturing and engineering hard-wired products to agriculture and food innovations, S & T lies at the cornerstone of development, but also represents contentious aspects that sometimes threaten the very existence of the industry that innovates in the field. Perhaps the best example of an S & T development that has been hailed as a great success while at the same time facing stiff societal reactions is that of genetically modified (GM) crops. In Europe, the debate around these developments is known as ‘the great GMO debate’.
The development of the first genetically modified organisms for human consumption was a turning point that redefined the relationship between science and the public in Europe. The advent of genetically modified soya in Europe in the mid-1990s, created a huge backlash from ordinary citizens who refused to accept scientific assurances on the safety of GM products. This issue, coupled with other concurrent food-safety scandals in Europe (e.g. BSE, dioxins), created barriers in industrial plans for innovation in the field, risking significant investments.

In addition, slow and inadequate reactions by policymakers deepened the feeling of public discontent and mistrust in science. As a result, Europe was faced with its first modern confrontation between science and society that, due to the need for public acceptance of the final consumer products, cost dearly in overall industrial competitiveness. There is still no consensus on whether policy developments in biotechnology innovation have been correct or not, but there is a general understanding that increasing interaction between science and society will help avoid similar situations; high-tech industrial developments require public consensus and the public expects to be well-informed and consulted over developments that have a direct effect on their lives. The establishment of SiS programmes is a direct consequence of these needs.

- Coordination of European research

The EU – like any other big regional entity – is a group of countries, each with their own unique development and socio-economic issues that are reflected in their respective S & T strategy needs. European publics differ in many aspects, including their views on S & T developments and their support of them. A good example is that of stem-cell research, where there is a sharp division of opinion amongst EU Member State publics, where religious and historical aspects of culture seem to directly influence public attitudes.

The need to understand national sensitivities and coordinate the various national S & T programmes in the EU require a common approach in the creation of SiS programmes. Comparisons between States, but also between publics with a similar background (e.g. education, urbanisation, religious beliefs), is essential in creating a coherent and successful S & T policy.
• Socially sustainable S & T strategy

SiS has been a means to improve S & T strategies by making them more socially sustainable. This means developing policies that create less opposition and friction in society, while at the same time promoting economic development and employment. This is possible only by exploring the social (including ethical) aspects of new S & T developments and offering the directly affected public a significant say in decision-making processes.

New methodological tools such as participatory technology assessment and foresight have been established to aid such aims, and the EU (within the usual State variations) has used them for a number of issues. The new forms of S & T governance are an integral part of the SiS programmes and are considered a major step towards the desired state of ‘knowledge-based society’ in European S & T.

**Aims of SiS programmes**

SiS programmes have specific aims on which their various activities are based and on which they are assessed (European Commission, 2007). Activities tend to change over time and are influenced by current needs but the overall aims remain unchanged as they represent the main ‘reason for being’ for the SiS initiative. The main aims of SiS programmes can be summarised as follows.

• Promoting scientific and educational culture in Europe

The new ideals of the ‘age of knowledge economy’ or the ‘knowledge-based society’ promote knowledge as the most valuable asset in the modern economy, and science as the most appropriate means for acquiring knowledge. In other words, the means and manner for achieving societal success in the modern world is through close acquaintance with S & T developments, gained through appropriate education. The term ‘culture’ is used to emphasise the plurality of ways in which education, science and knowledge are connected and consequently the different means that can be used to enhance this relationship. School education is only one of the many methods employed to reach this aim; practical experience, science shops, theatre plays, etc. are also used to promote the desired scientific culture.
• Putting responsible science at the heart of policymaking

A truly scientific culture that promotes a knowledge economy in society should be evident at all levels of decision-making. Whether regarding an individual decision on a personal matter or a political decision that affects the whole of society, science sometimes has an important role to play. It is nevertheless not evident what ‘good’ science is on any given issue. One might say that policymaking in S & T-related fields has become as complex as S & T itself. In this era of high specialisation, it is sometimes difficult to separate good science from bad science, and policymakers usually lack the knowledge and understanding to make this assessment.

SiS programmes aim to improve the quality and effectiveness of policymaking in S & T. In essence, this requires policymakers being involved in activities as much as ordinary citizens. Moreover, policy advisory structures such as technology assessment and foresight are increasingly becoming the main target of research due to their proximity to and importance in policymaking. Good advice leads to good decisions and vice versa and, therefore, improving advisory structures has a positive effect on policies (Decker and Ladikas, 2004).

• Stimulating continuous debates on scientific issues

Debates on S & T developments usually take place as a result of a scandal, particularly those related to health issues. At this stage, debates often take shape more as exchanges of accusations and blame rather than exchanges of information and attempts at consensus. Therefore, it is important to keep a constant flow of opinions and ideas around new S & T developments and promote, whenever possible, a common approach to decision-making.

Naturally, such a continuous exchange of ideas and opinions amongst stakeholders is a very challenging aim. It is not only logistically difficult to bring different stakeholders together on a particular issue, but it is also complex to decide who is a stakeholder, how to create common understandings between different perspectives, and, finally, how to implement possible suggestions for action. Various methods have been developed to ease the process of public debates and make them increasingly inclusive of different views and approaches. From regular public surveys to stakeholder workshops, SiS programmes are offering the means to promote socially valuable debates on S & T issues.
The main challenges of SiS programmes

Creating synergies between science and society would never be an easy undertaking. The success of such programmes depends on many factors, some more and some less predictable. Examples are the following.

- Political will

Since the mid-1990s, when SiS programmes became well-established, there have been many policy papers in Europe praising the contribution of S & T in economic and social development and promoting the need to keep society firmly involved in science policymaking. Nevertheless, on many occasions, policymakers have been faced with a choice between scientific demands and opposing societal demands, where a choice either way would be equally unsatisfactory[2]. Such situations have aided the realisation that societal values need to be embedded in scientific processes, and dialogue is the best means to achieve this.

This does not mean though that policymaking processes are in better shape as a result of such dialogues. It takes a strong political will to keep the promise of societal involvement in S & T if that means policymaking becomes more complex and demanding, and if that means taking a decision opposite to one’s instincts and beliefs. It is not yet clear how much of the required political will exists.

- Framing science issues

When discussing scientific issues, it is necessary to decide early on what these issues actually are, what choices they entail, who the relevant stakeholders are and to identify the decision-making process that should be followed. In short, it is important to ‘frame’ the issue correctly from the start. Inappropriate framing could result in social friction since the results of the discussion would inevitably lead to incorrect conclusions. For instance, a discussion on energy resources that does not take into account local voices in areas of resource development could lead to unsustainable decisions as they might be faced with strong local opposition. Similarly, an issue that involves a specific S & T development but is

---

2 A good example is the introduction of genetically modified foods in the market. While established scientific risk assessment processes approved such products for human consumption, the public demanded a ban on such products on the basis of their own value judgements. For a policymaker, this is a case where any decision has important ramifications while making those on one side of the argument feel (justifiably) unfairly treated.
discussed only in terms of economic development (such as job creation) could lead to wrong conclusions if other important perspectives (e.g. religious or similar value systems) are not taken into consideration.

- Methodological pluralism

As there is no one perspective on what SiS is and what it should entail, there is also no single perspective on the best methods to achieve its aims. There is a plurality of SiS-related methodologies in Europe and elsewhere, each of them having its proponents and opponents. Despite the fact that variety in methodologies is generally considered an advantage by expanding the available choices, in reality there is strong competition for resources that harms the overall value of the field. Sometimes, particular methods are viewed so positively that most funding would be directed towards them, only to find out years later that the ‘experiment’ was not so successful after all. Meanwhile, time and funds have been wasted without an obvious advancement in promoting SiS.

This situation would need to change and a more balanced approach should replace it. This would entail proper impact assessment of SiS methodologies and a clearer decision-making process on the specific aims of the programmes. That should result in a state of the field where methodological pluralism and complementarity of methods is the norm rather than the exception.

- Knowledge integration

It is still a major challenge in SiS to integrate expert knowledge in specific scientific subjects with that of stakeholders that may entail strong values and opinions that are void of specialised scientific knowledge. This is probably one of the most difficult aspects of communication between science and society, particularly when the interaction is meant to end in a common understanding and strategy. Nevertheless, it is a prerequisite in every meaningful interaction in the field to integrate knowledge regardless of its origin. Various methods have been developed to amalgamate disciplinary and lay perspectives into a coherent whole. These usually require longer periods of stakeholder interaction and trust-building exercises, not unlike processes employed in conflict resolution.
The Chinese SiS perspective

China is the world’s most populous country with 1.3 billion people. It is also one of the fastest-growing economies in the world, projected to be the largest by 2025. During the last 30 years, the size of the Chinese economy has multiplied by 6.4 times, with an average annual GDP growth rate of 9.3%; the GNP per inhabitant has experienced an annual growth of 8.1%. In 2008, the country’s GDP passed USD 4.42 trillion, making the economy the third biggest in the world. The country has undergone a profound transformation in the past three decades, from a planned economy to a market economy and from an agriculture-based economy to an industrial one. Industry, which employed only 17% of the active population in 1978, now accounts for nearly 25% of economic output. This radical transformation is unique in world economic history.

The newly acquired wealth is nevertheless a source of social problems as traditional farming communities have found themselves excluded from the newly found economic prosperity. The result is rapid and uncontrolled urbanisation where poor rural people are forced to move into the big and rapidly developing cities of the eastern regions in search of employment and better living standards. This in turn is creating a new urban underclass of unskilled people who lack educational opportunities and proper health standards. It is unclear whether this situation will eventually put a check on the rapidly expanding economy but there is a general understanding that the economy will continue outperforming other main competitors as a result of heavy investment in innovation and S & T.

The innovation potential of China is proportional to its economic potential (MOST, 2006). In recent years, the ratio of R & D/GDP in China has shown a trend of continuous growth after years of stagnation. In 2000, it reached 1% for the first time, and in 2015 it is projected to reach 3% of GDP, thus overtaking that of most industrialised countries. One could say that the R & D/GDP ratio has passed the first important transition point and is entering a period of faster growth, as stipulated by the government’s strategy to bring it in line with other S & T-intensive economies.

A sign that the strategy is taking effect is that, since the 1990s, the number of scientific papers published in China has been increasing. The position of the country on standard scientific indices is a good example: China was 15th in the world by the amount of papers published in scientific journals in 1994, 12th in 1997 and eighth in 2001. The proportion of China’s scientific papers in the world
was 1.25% in 1987 and increased to 4.08% in 2002, which placed China sixth after the USA, Britain, Japan, Germany and France. But in terms of relative ratio of citation by which the quality of papers is measured, China is still lagging far behind that of developed countries, and the quality of papers as a whole and their international effect are lower, which indicates that China’s S & T development is at an initial phase of growth (Arvanitis and Qiu, 2004).

- SiS challenges

The impressive expansion of the Chinese S & T sector signifies the increasing importance of the country at a global level, but its pace has created a host of social problems, not unlike those that we witness in more advanced economies. The new-found capabilities to create economic wealth through S & T developments has produced a general euphoria about S & T but little discussion on its implications and adverse effects in everyday life. Moreover, the management system of S & T that is characterised both by centralised bureaucracies in the public sector and deregulation in the private sector creates additional barriers in the creation of an effective system of checks. Finally, the socio-economic inequalities that are produced by the rapid economic development form another hindrance in creating and enforcing appropriate S & T controls that are inclusive of the majority population. Recent food scandals have highlighted the limitations of the policy-making system and have begun eroding public trust in science.

A good case for the current state and problematic issues in the area of SiS is to be found in the biomedical research sector (Yang, 2003). Considerable advances have been made in genomics and healthcare research in China and the government has initiated a wide-ranging strategy to enhance research and services, part of which is to increase the number of biomedical students. The strategy has already paid some dividends in the increased number of students but this is not followed by enhanced consideration of proper research ethics guidelines. Recent scandals uncovering unethical and unscrupulous research in parts of the country have created a fertile ground for the introduction of ethics in university curricula. Although medical ethics has begun to be taught as a requirement course, the emphasis is on moral modelling and conflict avoidance rather than issues such as research and professional ethics, researcher–subject rapport, communication with the public, etc. which are more pertinent in the current situation. Moreover, there is a lack of appropriately trained personnel, interdisciplinary insight and input from social sciences and humanities research. The approach appears inadequate
and ineffective, while at the same time the need to educate researchers and the public alike is becoming more pressing.

Despite the many gaps, China is clearly entering the era of SiS programme development. Although not named specifically as such, a series of initiatives are showing a strong commitment to enhance science and society interaction. Regular public attitude surveys on S & T perceptions, closer analysis of the social implications of S & T developments, development of a professional technology assessment and foresight sector, and increased attention to ethics guidelines, are all signs that there is a momentum akin to that in Europe but specific to the country’s needs and sensitivities.

**Contents of this book**

It is with the above issues in mind that this book was developed. The main purpose of the book is to provide a first-hand analytic description of the different facets of SiS in Europe and China. As the field is large and diverse, the following chapters will concentrate on those aspects of SiS which are most crucial in our opinion. From an overview of the basic cultural differences that underpin activities in the two regions, to a detailed description of the main policy advisory structures and a case study of a currently key S & T field, the book offers the first overview of similarities and differences in the attempt to embed society in S & T policy.

The first chapter, ‘Research ethics: European and Asian perspectives, global challenges’, focuses on basic concepts in S & T ethics and differences between the two regions. As is evident in most S & T debates, perspectives and views are influenced by one’s belief system, which in turn is influenced by one’s cultural background. The internationalisation of S & T and the need to find common solutions to common issues makes moral differences more apparent than ever. This chapter attempts to take stock of such differences and suggest a conceptual route to overcome them.

The second chapter, ‘Embedding society in European science and technology policy advice’, provides a detailed account of the roles and functions of S & T policy advisory in Europe. With particular focus on the social aspects of the advisory process, this chapter attempts to define the basic aspects of S & T governance in Europe by analysing decision-making processes. Notwithstanding the great
European diversity, there are certain commonalities in the field that are evident in similar approaches across the region that define a common view of society’s role in S & T policy.

The third chapter, ‘Science policy advisory in China: structures and social perspectives’, offers a more descriptive view of policymaking processes in China and the manner in which advisory structures operate. This critical analysis provides a good overview of the issues and problems that face Chinese S & T policymaking and makes apparent the opportunities and limitations for science and society interactions in the country.

The fourth chapter, ‘Dealing with nanoparticles: a comparison between Chinese and European approaches’, deals with a case study that exemplifies similarities and differences between the two regions. Nanotechnology/nanoparticle developments are equally advanced in the two regions, resulting in similar problematic but different approaches to resolutions. This case shows a reality scenario in S & T policy developments that allows for direct comparison in the manner of dealing with them.

The concluding chapter gives an overview of the ‘lessons learned’ in this book and provides some thoughts on the next steps that are needed to bring the two regions’ S & T policy closer together under a common understanding.
References

Arvanitis, Rigas and Qiu, Haixiong (2004), ‘Regional innovation systems and science and technology policies in emerging economies: experiences from china and the world’, conference proceedings. Unesco, Beijing Office.


Yang, Huanming (2003), Science and society, Beijing Genomics Institute, Chinese Academy of Sciences, China.
1 Research ethics: European and Asian perspectives, global challenges

Nial Scott
1.1. Introduction

In this chapter, I wish to introduce some of the values and concepts that arise in research ethics in a European context compared to an Asian context. Bioethics expresses key concerns in the ethics of technology; an important focus involves how one ought to conduct research ethics and how to use technology in an ethically acceptable manner. It is important to note from the outset that ‘the Asian context’ does not give us one single perspective. Asia provides us with a range of very different cultures, traditions and ways of thinking. Michael Cheng-Tek Tai expresses this by asserting that ‘Asia as a whole is characterised by the widest cultural diversity’ (Cheng-Tek Tai, 2008, p.15). He identifies key cultures that shape Asian thought as Hinduism, Buddhism and Confucianism, but also Taoism, Shintoism and Islam. As a result, it is not easy to identify an Asian bioethics but there are common features to be found. He categorises these as: ‘humanisation and harmonisation between man and his fellow men’, found in Confucianism, Hinduism and Buddhism; ‘between man and nature’, in Hinduism, Taoism and Shintoism; and ‘between man and ultimate reality’ in Hinduism, Shintoism and Islam (Cheng-Tek Tai, 2008, pp. 15–16). Just as the Asian context provides diversity and plurality, so too does the European context. In presenting this material, it will be evident how diverse and varied approaches to bioethics and research ethics are in Europe. Some will be compatible and complimentary with far-east Asian approaches and traditions, and some may well be conceptually quite different. It is important to note that what is presented here is a perspective on values that are apparent in European bioethics and research ethics which in no way implies a preferential approach. Much can be gained from engaging in dialogue about these issues with different ethical traditions.

There is no uniform ethical tradition in European countries; rather a great deal of diversity exists as will become clear below. However, European approaches to bioethics are dominated by either utilitarian ethics, virtue ethics, or by deontological approaches and the predominance of the theory of principlism (to which I return below in more detail) and that reasoning about ethics starts with the individual’s orientation. The key difference between a Chinese and European approach to bioethics might superficially be seen to be between an approach that is focused on the community and an approach centred on the individual; however, the ancient stories of the medical healers Hua-tow and Tong-hung demonstrate the practitioner’s deep individual duty and obligation towards the patient reminiscent of the Hippocratic tradition and virtue ethics originating in ancient
Greece. Confucian thinking expresses this further in the need for each person to cultivate their inner good for the sake of others (Chang Tek-Tai, 2008 p. 19).

Although there are common aspects to European and Asian thought, there are also differences. For example, Wenchao Li identifies that the approach to ethics is rather different between Chinese and German students. He holds that Chinese students start from a macro social perspective, where the entire society is collectively given the capacity to solve ethical problems through regulation and the ‘ethical knowledge orientation’ towards science and technology. Scientists themselves then become the moral examples for people to follow. However, this opens up a discussion about the proper role of ethics. Is it only an issue of professional ethics and the conduct of the practitioner, or is there a shared moral outlook that goes deep into the heart of individuals and communities based on their philosophical outlook, so that the ethical behaviour of the scientist complements that of the citizen? It was noted in the report of the 2005 Science and Engineering Ethics Budapest meeting that in the political harmonisation of central European countries and the new Member States of the European Union, they do not have a shared body of ethical thought (van Steendam et al., 2005, pp. 778–779).

I will first briefly mention issues that have arisen from the past in European research ethics, some of which might be well known. These serve to highlight the difficult and sometimes disturbing history in relation to which the need for consensus on an ethical approach to research becomes clear, especially considering the vulnerable status of the research subject, whether as an individual or a community. However, as will become clear, consensus is not an easy task, and becomes more of a challenge when research ethics is opened out from the local to the pan-European level and even further to consider the diversity at the Asian and ultimately the global level. It is in the latter area that much work needs to be done regarding research ethics, in a spirit of dialogue and openness to a range of cultures and traditions. The need for some sort of consensus on research ethics arises with regard to securing the proper treatment of the research subject with regard to their vulnerability and potential exposure to great harm. Language and culture are significant areas that make this a considerable challenge, but as Ole Döring notes regarding Chinese–German culturally reflected bioethics: ‘Strong relativistic theories of a strong determination of ethics by language have still not provided evidence for their speculative claims of exclusion, whereas common sense invites reason to organise practice so that it can be governed according to universal ethical regulations’ (Doring, forthcoming).
This chapter will give an impression of European-held values in research ethics such as pluralism and solidarity, but also pay some attention to the tension between individualistic and communitarian ideas, and the perceived predominance of the North American theory of principism in European bioethics. This area is an ongoing dynamic discussion in the field of European bioethics, and it is worth mentioning Prof. Ruth Chadwick’s recent introduction of the notion of harmony as a crucial additional value in bioethics and research [European Society for Philosophy, Medicine and Health Care Conference, Estonia, 2008]. Perhaps the idea of harmony and harmonisation is a feature we can find in common with Confucian, Hindu and Buddhist thought. This piece finishes with a focus on the promotion of pluralism in the European context in the light of the goals of research, be they concerns for individuals or communities, such as the research community. This will lead to a discussion on how to cope with pluralism and whether the pluralistic approach is possible at all given the competing tensions and demands made by the different parties involved in research. I will not be dealing with the specific regulatory frameworks and guidelines that currently exist at a global and European level (although these may come up as illustrative of particular issues); the main focus here is on the values and ethical outlook that have an influence on such frameworks.

1.2. International guidelines on bioethics

Problems regarding research ethics and the lessons learnt from them have a well-documented history in Europe, and most of the improvements in the research culture regarding the treatment of research subjects centre round key events that have led to dramatic changes in policies and guidelines. One of the intriguing historical features is that the first country to develop and implement ethical guidelines for experimentation was Germany, hand in hand with this country’s rapid success in the growth of modern pharmaceutical industries. In 1900, the Prussian minister of religious educational and medical affairs insisted on a directive that medical experiments should only involve the use of competent adults who had been properly informed of the procedures including adverse effects of the experiment [McNeill, 1993]. Despite the well-known and well-documented atrocities carried out under the Nazi regime in Germany, there were legally binding guidelines that emphasised prior testing on animals, informed consent and restrictions on harmful experimentation on children. This period introduced the serious problem in research that identifies the tensions and conflicts between the individual research subject, the needs and goals of society and
the goals of the scientific community. It is important to note as well that from the outset of the regulation of research, government has been involved and ethical regulation has been built into policy.

The historical development of ethical regulation following the end of World War II in 1945 in Europe illustrates the tension between the demands of the research community and the research subject. The Nuremburg Code was drawn up as much as an expression of victory over the Third Reich as a genuine attempt to ensure that the abuse of research subjects as perpetrated under Nazism would not happen again. However, in the research community, the Nuremberg Code in its 10 principles was considered to restrict researchers too much as a legal document and was effectively replaced by the 1964 Helsinki Declaration, which concerned itself more with the roles and responsibilities of researchers.

Furthermore, the rapid growth in experimentation and the tragedies experienced in the USA and the UK in the thalidomide research scandal, amongst other deeply problematic research activities, created the need for a new ethical framework. The emphasis on protecting the research subject is captured well in the Declaration of Helsinki, in its principles governing harm, consent and the provision of information for the research subject. For example regarding harm, Principle 5 states that: ‘Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society’, (WMO, Helsinki Declaration, 1996). This then places a high degree of emphasis on the well-being of the individual. Nonetheless, the Helsinki Declaration also favoured researchers, as it opened up possibilities of research on subjects through proxy consent if required, and even that consent was not required if a doctor/researcher considered the research to be in the patient’s interests.

In the Helsinki Declaration, we have the first distinction between therapeutic and non-therapeutic research. Therapeutic research is where the patient benefits from research regarding its diagnostic and/or therapeutic outcome, whereas biomedical and clinical non-therapeutic research does not have a direct value for the patient and is largely pursued for purely scientific purposes (Brody, 1998). In 1982, the much more detailed CIOMS (Council for International Organisations of Medical Science) guidelines were developed in collaboration with the World Health Organisation (WHO), a document that (like the Helsinki Declaration) has been continuously updated and revised. The CIOMS document places the
emphasis back on the protection of the research subject, by introducing the need for independent representative bodies be involved in the development of research (effectively now recognised as research ethics committees). In addition, a European Community conference with the WHO in Canada in 1988 introduced a principle that: ‘a nation should not allow or support other countries’ research which does not conform to ethics review standards at least equivalent to those in force within the nation’ (Miller, 1988).

The most recent version of the Helsinki Declaration, adopted at the 59th WMA general assembly in Seoul in October 2008, holds that: ‘12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on thorough knowledge of scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate animal experimentation.’ Article 16 holds that: ‘Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications’ (WMA, Declaration of Helsinki, 2008). This is not an easy point to uphold or negotiate where there are different scientific traditions and practices in different nations. These principles are likely to lead to conflicts where differences exist between traditions as to what counts as appropriate scientific training or what counts as generally accepted scientific principles. For example, Ayurvedic medicine, practised in India and surrounding countries, is radically different in its more holistic approach from western medicine. Likewise the practice of traditional Chinese medicine (TCM) faces the challenge of whether it ought to be subject to clinical trials and randomised control trials (Renzong, 2008, p. 50) in order to complement the demands of the Declaration of Helsinki. TCM is individualised for the needs of each patient, and its practice varies from one doctor to another with the non-standardisation of drugs and a complexity of ingredients of which the individual contribution is not known (Renzong, 2008, p. 50), which all pose problems for a uniform approach to research ethics. However, TCM can benefit from clinical trials in the safety and effectiveness of treatment, and combinations of TCM and other types of treatment can be tested against each other, and complex recipes can be treated as a whole, rather than trying to break them down into component parts (Renzong, 2008, p. 50).

These latter principles presents us with very serious challenges regarding the increased recognition that very different moral and cultural values may be adhered to within Europe and Asia, which is captured by the suggestion that pluralism ought to be embraced in the research environment in Europe. As we shall see in lessons from the present below, this is not without its problems.
1.3. The tension between bioethics theory and practice

Recent times have given strong indications that research ethics continues to face many challenges. One of the major shifts is moving into a time when the Human Rights Act is being used to increasing effect in the support of patient and research participant’s welfare. An area of difficulty, especially in the United Kingdom, is the relationship between ethical regulation and law. Where there are many directives and guidelines, and a close relationship is observed between obtaining funding and ethical approval being given to research projects, there are still some key problems confronting research ethics. I propose that the majority of these problems arise in the goals of research. This is particularly noticeable in conflicts of interest that can easily arise between on the one hand, research driven by corporate goals and the interests of developing knowledge and certainty from a ‘pure’ research interest, and on the other the welfare and goals of the research participant. Such problems also confront the Chinese situation where the operation of market forces in healthcare and research is the norm, but where ever-increasing attention is also being paid by the Ministry of Health to the protection of human research subjects through the implementation of regulations (Ministry of Health, 2007).

An example of these problems can be seen in cases where a medical researcher enrols patients in a drug trial that includes an obligation to the development of a new product with funding from a pharmaceutical company. This can result in a threat to the medical professionals’ obligations of care to the patient. Furthermore, in such a situation, the medical researcher/doctor has changed their role in relation to their patient: initially the patients need the doctor for medical care; in research, the doctor as a medical researcher needs the patient, who has become a research subject or participant in their care. Complications arise when public interests are added to the situation, say in the results of the research, and decisions regarding ethics become more and more difficult to attend to when the involvement of an ethics committee represents a range of parties (Ashcroft, 2004).

We can broadly identify and divide research goals as being directed towards either individuals or communities. If it is accepted that we need to carry out research for there to be progress, then one may think that the interests of individuals, whether healthy volunteers or patient volunteers ought to submit to the broader aims of improving the quality of life of others, society and future communities. The implications of this tends towards a downplay of the interests of individual participants, but their welfare can still be looked after. However, despite
safeguards, problems still occur. Renzong Qui states that the purpose of regulation is to develop biomedicine and biotechnology to save millions of patients and for the protection of the welfare and rights of human subjects. However, he also notes that some scientists in China think that such protections impede scientific progress and that ‘China should surge ahead without constraints, in advancing its scientific and technological endeavours in order to catch up with them’. Qui states that this position is wrong and dangerous, referring to the scandals of the Chen Jin case in China. (Qui, 2008, p. 48).

There are many challenges ahead for both the European and Asian research world in the implementation of regulations, and even when the research culture does try to adhere to correct protocols, problems still arise as the following example shows. In 2006, in the United Kingdom, six men who had taken part in a drug trial for the anti-inflammatory drug TGN1412 were taken ill and admitted to intensive care. The research was at phase one testing of the drug on humans. It appeared on investigation that the German drug company, TeGenero, had followed correct clinical procedures, although there were questions regarding unpublished work done on animals prior to phase one testing, and the company was criticised for some minor procedural irregularities. However, the results leading to the six healthy volunteers suffering from acute organ failure were deemed to be completely unexpected and rare. The Medical and Healthcare Products Regulatory Agency (MHRA) stated: ‘We are satisfied that the adverse incidents which occurred were not as a result of any errors in the manufacture of TGN1412, its formulation, dilution or administration to trial participants’ (Woods, 2006, MHRA Chief Executive, Clinical Trial Final Report).

This example shows that even where procedures, guidelines and protocols are followed, the issue of uncertainty in research and adverse results can not only (obviously) place a burden on the volunteer subject in the anticipation of harm and risk, it also places the research community under a great deal of pressure. This is the case even when, following scrutiny of the research, ethical procedures have been followed. We can identify areas of tension from this recent example, where there can be competing demands made in research regarding its proper conduct. This concerns:

- the individual, as:
  - the participant;
  - the benefactor of the research;
  - the healthy volunteer (altruistic, as in the TGN1412 example above);
  - the patient volunteer (requiring therapeutic benefit).
the research community with its interests:
- as a scientific community;
- as a corporate community;
- the wider human community benefiting from the research.

Regarding the research community, some important lessons can be learned from tensions between the demands being made on researchers through ethical regulation and the development of increasingly more strict guidelines. This concerns the problem of the length of time devoted to the ethical approval of research. On the one hand, stricter guidelines offer more safeguards and protections to research subjects. However, in a well-regulated region, this can impede research development, which might then be carried out in a less regulated environment.

A good example of global problems relating to regulation and policy development in research ethics is in the arena of stem cell research. Alka Sharma (2006) identifies the range of differences that exist, not in the goals of stem cell research, but the means employed in obtaining stem cells. In other words, the point at which the research interacts directly with human subjects. Thus, some countries have developed liberal policies, others quite prohibitive ones. This variation is reflected globally: Germany prohibits the derivation and use of human embryonic stem cells from blastocysts; Ireland has a legal ban on the creation of human embryos for research purposes (and for the generation of stem cells); Scandinavian countries permit the use of human embryonic stem cells from supernumerary embryos; the more liberal Chinese approach permits research on human stem cells if, and only if, derived from surplus IVF embryos and those created by nuclear transplantation; in India, approval is required from the Institutional Committee for Stem Cell Research and Therapy as well as the institutional ethics committee, provided consent is acquired from the donor (Sharma, 2006, pp. 51–52). This example shows that the interaction between regulatory frameworks and local expressions of ethical values can lead to very wide-ranging research restrictions.

In the current development of the EU clinical trials directive, which was first implemented in 2004 and is currently being revised, improving the protection of patients and research reporting reliability were the main goals. Although this sends a comforting message to participants in clinical research, complaints have been voiced in the research community that the increased bureaucratisation of the research process has damaged access to new treatment, slowed the research process down, with a reported five-month addition to trial initiation because of
the added workload given to ethics committees. This can cause damage to patients who could benefit from new drug development and treatment access. This is clearly a difficult issue, where the goal of research – in this case medical research – as benefiting others, i.e. the wider community in need of improved treatment or access to new drug regimes, comes into conflict with the interests of individuals as research participants (Hemminki and Kellokumpu-Lehtinen, 2006). However, in much clinical research, the participant in trials (especially phase two and three drug trials) will also be a beneficiary of the research, being both a patient and a volunteer.

1.4. Ethical approaches and European values

The range of values expressed in the bioethics literature in the European context is quite staggering. Some of these are articulated through long-standing moral theories, some are an expression of the American interpretation of and influence on the discipline of bioethics, and others have emerged in recent attempts to identify and develop a more unique European set of bioethics values. All of these have a bearing on the conduct of research, in that they lead to quite differing ways of interpreting research ethics guidelines and research policies. Hope, Savalescu and Hendrick, in their work on the core curriculum concerning medical ethics and law in the United Kingdom (2008), relate three identifiable ethical approaches in research ethics. These are firstly, libertarian (rights based); secondly, paternalistic (duty based); and thirdly, utilitarian (consequentialist) ethical positions (Hope, Savalescu and Hendrick (2008), p. 220).

Given the complexity of ethical issues in research, there seems to be a developing tendency not to follow one particular moral framework, but to develop appropriate moral responses to situations as they arise. Most of these are familiar territory. So where a situation calls for the protection of an individual’s interests, say for example by defending their autonomy, a Kantian approach may be the best fit. Utilitarian theories may be most appropriate in ethical decision-making where a situation is affected by the outcomes of the research approach. Where care is paramount, or when the professional conduct of researchers is called into light, a virtue ethics approach may be more suitable, and virtue as a broader moral theory may well cover a wider range of situations. Of course, there will be those who hold fast to and defend a single moral approach to research ethics. The result is that the research ethics community nowadays appears to provide us with a plurality of ways in which moral problems can be dealt with. Principlism,
the approach championed by Thomas Beauchamp and James S. Childress (2002) reflects this in treating ethics as an activity of balancing the competing demands of justice, autonomy, beneficence and non-maleficence that arise in any given research situation. Furthermore, some of these aspects feature strongly in European human rights legislation.

1.5. The influence of principlism

Principlism has had a significant influence on thinking about bioethics and research ethics. It forms part of many teaching and training programmes in ethics worldwide. Beauchamp and Childress have sought to take significant aspects of European moral traditions and work them into an overarching ethical approach that is oriented to problem-solving by balancing four values identified in these traditions. These are the principles of justice, non-maleficence, beneficence and autonomy, also known as ‘the Georgetown mantra’ after Georgetown University where Beauchamp and Childress worked when they developed these ideas. They are not dissimilar to the values reflected in the 1979 Belmont report following the Tuskegee syphilis study controversy, which were respect for persons, beneficence and justice. Brody notes that these three principles form the moral basis for many official policies (Brody, 1998, p. 35).

The approach of principlism has frequently been criticised for introducing too much of a North American perspective into European bioethics, but as Matti Häyry points out, this accusation fails to take into account the European origins of the theories and approaches it is based on (Häyry, 2003). Beauchamp and Childress’ ideas on autonomy make much use of a Kantian conception of the human agent as rational and capable of making rational self-directed choices; the ideas concerning beneficence and non-maleficence derive much of their content from utilitarian cost benefit thinking and Kantian notions of the duty to be altruistic (Scott, 2006, Imprints). The principlist approach then taps into the deontological and consequentialist ways of thinking mentioned above. Principlism is also criticised for trying to cover so much ground that the four principles can be made to mean anything and thus when applied lead to conclusions that are conceptually incompatible. For example, the principle of beneficence can be employed to support an altruistic duty as obligatory, but can also be used to consider the extent to which one is required to be beneficent depending on the consequences. This has an important impact on the way a research subject could be treated. An attempt was made, as expressed in the Barcelona declaration (1998) to promote
autonomy, dignity, integrity and vulnerability as a closer expression of European values in bioethics.

### 1.6. Solidarity and dignity as European values in research ethics

A further issue highlighted in the above approaches is that they tend to emphasise individualistic ways of thinking in European ethical values. However, it would be mistaken to assume that European values in ethics are predominantly individualistic and thus radically different from, say, a Chinese perspective which is perhaps characterised by being more open to communal values. Indeed Matti Häyry (2003) has suggested a set of values, namely dignity, precaution and solidarity, which focus more interest on the important communal component of ethics. Solidarity and those who find themselves in relationships of solidarity, are likely to defend one another’s interests and rights, and even their individual and shared identities. It is thus a powerful value when considered in the research context for human and especially vulnerable subjects. Solidarity is most widely associated with political movements and especially the working class movement in industrial contexts. Dignity reflects both the religious and spiritual legacy that European ethics has been based on and provides for a diversity of interpretations that feed into the pluralistic nature of European values. It is found in Christian/Catholic teaching, where it can be linked to the doctrine of the sanctity of human life that includes the irrational and the unborn (Häyry, 2003, p. 204), and in the Kantian expression of worth, where dignity is a condition of rational agents (Kant, 1999, pp. 434–435). Häyry also refers to the recent use of dignity in connection to human genetic identity in the Unesco Universal Declaration on the Human Genome and Human Rights which is worth quoting, as it expresses limits to research regarding human cloning:

*The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity... Everyone has a right to respect their dignity and for their rights regardless of their genetic characteristics... That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity... Practices which are contrary to human dignity such as reproductive cloning of human beings shall not be permitted.*

[Universal Declaration on the Human Genome and Human Rights, 11 November 1997, paragraphs 1, 2 and 11, in: Hayry, 2003].
This links dignity to the scientific view of human beings, including artificial generation of humans.

Solidarity is a value that emphasises relationship, community and reciprocity. It can be treated as a value worth promoting because it is universally considered good for individuals to be solidaristic. However, to conceive of solidarity in terms of individual actions in relation to the State, for example, is to miss the very thing solidarity captures, a mistake that Charles Taylor notes in his criticisms of individualism. Taylor holds that the common understanding held in the practices and institutions and ways of living in a society, cannot be reduced to individuals and their thoughts and solitary actions (Taylor, 1990). Thus, where common understanding is a property of the group, so too, I think, is the value of solidarity. It is a value held in common and expressed communally with others, often with a particular goal in mind. Solidarity must be held in tension though with the appropriate perspective on human dignity, as on its own, solidarity can be identified as a property of many groups that are focused on unethical goals. Dignity can hold solidarity in check.

1.7. Pluralism in global ethics: is it possible?

I have shown that there are a plethora of values that are currently being debated in the context of bioethics and research ethics. At the beginning it was held that the Asian contribution to bioethics is based on a range of cultures, traditions and perspectives; so too is the European contribution. These represent some of the ways of thinking that have an impact on decision-making in ethics and policy in a global context. It thus seems to be the case that it is appropriate to speak of pluralism in the European situation. But if we introduce this, it can either be done in an attempt to recognise the range of values or to have some overarching descriptive term that covers a series of contesting and sometimes competing series of claims. It can also introduce pluralism as a moral theory, as an independent heading in addition to the moral perspectives previously mentioned in this chapter.

Sakamoto’s well-known and important contribution to bioethics from an Asian perspective applies more generally to a possible global approach that promotes holistic harmony rather than atomistic individualism. His aim is to move from Asian to global in a challenging proposal that this must be grounded on the traditional ethos of each region which might be quite different from the European
one in many respects’ (Sakamoto, 1999, p. 197). It seems that the only way to do this is to embrace pluralism rather than the relativism which Sakamoto promotes. However, Sakamoto saw a tension in the development of bioethics in some Asian countries in relation to protecting the values and norms of their societies, as well as their social prosperity, that would refuse to accept western models of ethics based on concepts of human rights and human dignity. He cites the Chinese one-child policy and western ideas on eugenics as an area of conflict (Sakamoto, 2002, pp. 52). For Sakamoto, a global bioethics is based on adopting a holistic approach that goes beyond western individualistic utilitarianism (Sakamoto, 2002, p. 54). But this is to ignore the diversity of ethical approaches to be found in the European context; there may well be components of western individualist utilitarianism that are worth preserving or learning from, in the same way that there are bound to be features of traditional Chinese medicine or Ayurvedic practices that are invaluable in expanding understanding in western scientific approaches in western ‘evidence-based medicine’.

Writing at the same time and complementing this, De Castro supports a pluralistic approach in bioethics, but one that accepts a universalism of goals:

In a world characterised by increasing cross-cultural encounters and ethical pluralism, we cannot abandon the drive for universal acceptance and understanding. However, the universality of our ideals cannot be found in a single standard that is common to all outlooks, but, rather, a collage of cultural informed perspectives built upon ever-increasing aggregate of shared experiences.’ (DeCastro, 1999, p. 234).

The aim of securing protection and better conditions for human research subjects through the development and revision of regulations and policy in research is such a universal goal. The way to achieve this goal needs to take into consideration the diversity of cultures and traditions that we find.

Perhaps what the European experience is heading towards is a more thorough pluralism that could create serious problems with regard to research ethics. In the recent EU opinion document on ethics and nanotechnology, the authors state that pluralism is a characteristic of the European Union (2007). One may be moved to wish to extend this as a global characteristic. In the area of research ethics, the document insists that pluralism be upheld and that ethical standards that develop in this culture do so within the constraints of the principle of respect for the rights of individuals, respect for multiculturalism, dialogue and tolerance.
However, there are serious problems with the idea of pluralism in the above. Is pluralism the best way forward in dealing with a multitude of values and demands?

- Pluralism needs to be clearly defined – there are, for example, differences between the meaning and effect of social pluralism and moral pluralism.
- It may be that pluralism allows a kind of moral laziness, where ethical approval will eventually be found as long as the desired moral approach can be matched with the research to be carried out.
- Pluralism can also open the door for approaches that ought not to be tolerated, but can slip in under the disguise of cultural difference.
- Pluralism simply cannot resolve genuine disagreement when moving from a theoretical consideration of research ethics issues to the implementation of the research programme in practice.

This genuine disagreement can be at the level of the research community, as is the case in clinical equipoise. Or it can be a disagreement between the interests of the individual and that of the community, where for example an individual’s welfare may be threatened while the research goal aims at benefitting a greater number of people (such as in the trial of TGN1412 outlined above).

Medical improvements and research development aimed at improving the quality of life of humanity in general, simply cannot be done without research. How can we be hard-headed about the need to use research participants and face up to all the risks involved to them and at the same time provide safeguards, so that harms are minimised? This is the ongoing challenge facing the development of ethical regulation in a world of differing ethical values. It is not clear how pluralism and the aim to keep all sides happy in this atmosphere of competing goals and different values is going to deliver the required response to this challenge. Above all, however, is the need for safeguards that protect the research subjects, both as individuals and/or as a community: it is the research subject who is highly vulnerable and all too easy to exploit in the name of research progress.

The challenge then is how to move forward. Soraj Hongladorom holds that we can move beyond an east–west dichotomy (Hongladorom, 2008, p. 13). The demands made by the proper ethical treatment of research subjects are going to be the same irrespective of context and culture, but that context and culture need to be recognised in bioethics and regulation are going to be a common concern for both eastern and western perspectives. Prof. Huanming Yang notes that the social responsibility of a Chinese human geneticist is not different from that of
colleagues in other countries and he does not think that there are serious discrepancies between Chinese attitudes in pursuing an ethical approach to research and others (Yang, 1998). The emphasis ought to be on how a particular moral value is applied in a certain context which then informs ideological debates. Mistakes will be made, but these can be continuously minimised as each context moves through the process that underpins moral and bioethical discovery, for ever improving the manner in which people are treated as research subjects and as patients. This requires openness and a willingness to share problems and successes, in dialogue that brings cultures and perspectives together.

References


Embedding society in European science and technology policy advice

Leonhard Hennen and Miltos Ladikas
2.1. Introduction

The European science and technology (S & T) sector is amongst the most diverse and advanced in the world. Despite great diversity amongst European States, taken together as a single region (i.e. the European Union), Europe is at the global forefront of S & T developments and its economies are directly impacted by the outcome of its numerous research and development (R & D) programmes. EU Member States dedicate roughly 1.84% of their GDP to S & T and there is a clear will to increase expenditure to 3% of GDP in the coming years. Overall S & T expenditure is second only to that of the USA and the political ambition is to top the world ranking in the next decade. In terms of S & T output, Europe is leading the world in many aspects: it has the highest number of scientific publications in the world, the highest number of R & D personnel, the largest share in high-tech export products and the highest number of patent applications [Eurostat, 2008].

The successes that we witness in European S & T are probably the result of a widespread education and scientific culture that emphasises resourcefulness in problem solving and ambition in individual development. But this is by no means a unique or a guaranteed tool for success. On many occasions, scientific developments that have derived from conventional wisdom and conformed to conventional risk assessment, have failed to gain societal acceptance and reach their potential. The reasons for such scientific failures have been the subject of intense inquiry since they are viewed as a warning for future problems that could threaten the very existence of entire S & T fields. Policymaking in Europe has taken stock of the problematic that sometimes surrounds societal acceptance of scientific developments and has sought help in examining cause and effect relationships. The ultimate aim of such endeavours is not only to avoid technological failures but also to create S & T programmes that promote economic development without jeopardising social coherence.

The field of technology assessment (TA) was developed as the main policy advice on S & T developments and was naturally the prime candidate to take the leading role of researching social aspects of S & T. This chapter offers a detailed analysis of the history of TA as policy advice, its expanding role in relation to social aspects of S & T and its current efforts to firmly embed society in its work in S & T policy advice. This is a uniquely European story that nevertheless has important ramifications in world developments, since S & T policy is increasingly faced with similar issues in every region of the world that might necessitate similar analytical processes and eventual resolutions.
2.2. History of TA

2.2.1. Background: the consequences of technical modernity

Structures or institutions to advise science and technology policymaking are manifold in most industrialised countries. Ministries and their departments usually cooperate with a group of advisors from science and industry to develop S & T programmes for different fields of R & D. Most European countries have established research councils of independent high-level experts that advise governments with regard to upcoming new fields of R & D, setting up programmes for R & D funding as well as developing relevant research institutes. Often, national research councils are entitled to evaluate the performance of public research institutions and give recommendations for their further development. These advisory structures are dedicated to deal with – as it were – the internal matters of the national R & D landscape; its nourishment, maintenance and development as a national source of wealth and welfare.

Since the 1960s, however, a new set of questions have entered the scene of S & T policy; questions about the relationship between science and society and the external effects of technological development on the environment, society and economy. With emerging public conflicts about new technological developments and S & T programmes, it became obvious that policymaking was lacking the means for steering technological developments in a way that was accepted as socially sound or reasonable by a broad range of social groups. Governments were confronted with a new task to be taken up in the realm of S & T policies: besides funding technology and supporting the development of a powerful national research system, there was apparently a need for precaution against undesirable effects of modern technologies. New demands for steering technological development (articulated often by manifest social conflict on the introduction of new technologies) were directed at the State. Deficits in the market economy that lead State research and technology policy into fostering basic innovations, make it clear that proper consideration of unintended impacts cannot be left to self-regulatory processes of the market.

The concept of TA, which has its origins in the late 1960s in the USA, can be regarded as a response to this situation, further induced by the growing importance of S & T in social development and the political need for new requirements to deal with complex S & T problems. TA had originally been conceptualised as a procedure of scientific policy consulting, i.e. essentially a process of
communication between experts and decision-makers. TA aimed to broaden the knowledge base of policy decisions by comprehensively analysing the socio-economic preconditions as well as the possible social, economic and environmental impacts of the implementation of new technologies. In this respect, the expectation that rational political planning should be possible with better scientific analysis of issues was at the core of TA. However, beyond any technocratic notion of finding the one best solution for societal problems by proper scientific analysis, TA also began to be regarded as a reaction to the apparent shortcomings of this kind of technocratic planning optimism. The more it became apparent that living conditions in modern societies are dependent on S & T developments, the more policymaking had to face the fact that the relation between science and policymaking is more complex than is often assumed by simplistic technocratic thinking.

Social conflicts and controversies reflect risks and uncertainties which cannot be dissolved by relying on scientific data and concepts alone. There is no way of escaping the complexity of decision-making processes that include different contradicting values and objectives as well as different social interests and demands (Hennen, 1999). Science cannot support policymaking by reducing uncertainty of decisions via reducing complexity. On the contrary, S & T might increase uncertainty in decision-making by revealing the full complexity of the issues at hand, while not being able to provide definitive answers to questions which are central in policymaking.

During the last decades, participatory approaches gained particular relevance in TA (see contributions in Joss and Bellucci (eds) 2002). This is partly due to growing awareness of the shortcomings of a ‘technocratic’ TA approach, which was based on the (at least implicit) assumption that TA could deliver solid scientific knowledge about future developments, thus giving definite advice to decision-making. The history of TA then, can be seen as a learning process regarding the limited possibilities of improving planning and programming in political decision-making through scientific knowledge. Such limitations arise from the intrinsic uncertainty and probability attached to assessing issues with future potential. Furthermore, the field of technology policy has recently been dominated by intensive technology controversies on questions of risks and ethics (e.g. the issue of genetic manipulation of life-building blocks). This indicates the fundamental problem that every assessment of technological development has to refer to values, which are by no means uncontested in society.
2.2.2. The institutionalisation of TA

The increasing importance of problems associated with policymaking in the field of S & T in the 1960s led to discussions about TA (initially in the USA) as a new concept of analysis and policy consulting that should help to steer the course of technology development. This concept gained prominence in all western democratic States in the 1970s. Technology assessment was taken up by many institutions, in academic research and at universities. The institutional focus of TA, however, has always been on advising governmental bodies.

In particular, national parliaments have always been regarded as the main addressees and clients of TA. As the parliament is seen as the main representation of the public in policymaking, it has to be transparent and inclusive of societal values in debates on new technologies and their impact on society. But parliaments were initially lacking appropriate access to the scientific expertise that was needed to deal with most advanced S & T developments. Whereas governmental administration in ministries in the 1960s had already built up large departments with scientifically trained staff involved in setting up S & T programmes, parliaments (the bodies for controlling government on behalf of society) were in need of support for keeping track of new developments in S & T. TA has thus always been regarded as a concept to be applied (not exclusively but mainly) by the legislative body of governments in its attempts to control the executive’s power in fostering S & T developments.

A major step in institutionalising TA as a particular branch of policy consulting was the establishment of the Office of Technology Assessment (OTA) at the US Congress in 1972. Congress intended to provide for a broad knowledge base in its own deliberations and decisions by creating an institution that should be able to inform legislators on any new developments in S & T and should function as an ‘early warning’ facility with regard to possible problems and needs for political intervention. OTA carried out hundreds of influential studies on behalf of both Houses of the Congress and employed up to 150 scientists. Its philosophy of unbiased, although clearly policy-oriented, analysis of risks and benefits of advanced technology developments inspired similar parliamentary institutions in many European countries. Consequently, discussions on TA in Europe led to the foundation of a series of TA institutes related to national parliaments in the 1980s and 1990s. The idea of TA was widely established in Europe when in 1996 a new Republican majority in the Congress surprisingly decided to close down OTA. The decision was taken in a climate of debates about reducing State interventions in
regulatory processes and also reducing governmental expenses. The close-down of OTA has been regarded as a sacrifice to this 'zeitgeist' but also as a result of its close relationship with influential deputies, such as Democratic Senator Edward Kennedy. It has been speculated that one of the main motives to abolish the OTA was that it was regarded as an 'institution of the Democrats' (Herdman and Jensen, 1997; Hill, 1997).

Ironically, however, at the same time that OTA was closed, TA – as an import from the USA – had already become a major success in Europe. Today, the European Parliamentary Technology Assessment Network (EPTA) comprises 13 national parliamentary TA institutions, including the TA body of the European Parliament, while there are another five associate members with close relationships to their national parliaments. Parliamentary TA in Europe took up the heritage of the OTA but differs in many respects from it, organisationally as well as with regard to methodology and mission (Vig and Paschen, 1999). Parliamentary TA bodies in Europe are organised in the European Parliamentary Technology Assessment Network (EPTA). (For an overview of current activities of EPTA members’ activities see the TA database at: www.eptanetwork.org).

Different institutional models are followed in different countries, depending on their political and/or parliamentary traditions and cultures. In some countries (such as Italy, Finland and Greece), parliamentary committees for TA have been established which – according to their agendas – invite experts to their meetings or organise workshops and conferences in order to gain scientific support for their deliberations. In France, individual members of the committee carry out TA studies on their own, and deliver the results in the form of reports to their parliament. In other countries, parliaments have chosen a model of institutionalisation closer to the OTA type. The parliament then runs a scientific office on a contract basis with a scientific institute (such as in Germany and at the European Parliament) or as part of the parliamentary administration (such as in the UK) to which TA studies are commissioned according to the information needs of the parliament. These studies may result in short parliamentary briefing notes or in fully fledged TA reports, drawing on their own research and also input from a number of external scientific experts and stakeholders.

A third type of parliamentary TA bodies is characterised by close cooperation between parliaments and external independent institutes (in some cases related to the national academies of sciences) that support parliamentary deliberations with policy reports and organisation of workshops or hearings. Often this kind
of arrangement involves an additional mission of the institute which opens up the classic (OTA-like) TA setting of experts and policymakers to an additional third party: the general public. The mission of TA then is not only to support politics by providing in-depth and unbiased analysis of the possible effects of science and technology on society, but also to inform and intervene in public debates (such as in Denmark, the Netherlands, Switzerland, Belgium (Flanders) and Norway). This kind of orientation of the consulting process towards the public, stakeholders, societal groups and citizens, can be regarded as the European ‘improvement’ on the classic TA model. The classic model also viewed societal values and interests as an indispensable prerequisite of TA when evaluating technology impacts. Contacts with societal groups in the form of interviews, workshops, etc. have always been part of the TA process. Nevertheless, in the new ‘public’ or ‘interactive’ model of TA, society plays a more active role, and participatory methods (such as scenario workshops, focus groups and citizens’ conferences) have been systematically developed and applied in order to give the public a voice in the TA process, and, at the same time, initiate and stimulate public debate about the issues at stake (for the latter purpose, events such as science festivals, conferences etc. may also be organised by a TA institute).

Against the background of these three models of institutionalisation – the ‘committee’, the ‘office’, and the ‘interactive’ model – it is apparent that TA plays an intermediate role with regard to three societal arenas: science, politics and the public sphere (see Figure 1). Which of the three models is in focus varies according to dominant political cultures. However, any TA institution has to position itself in this triangle, and can have the role of translator or mediator between science, society and policymaking at the same time. Working according to the ‘classic’ model of scientific policy consulting does not imply a ‘closed circle’ type of policy advice where experts and policymakers negotiate behind closed doors. The TA process must always be transparent to the general public and especially for social groups that have a stake in the particular issue. As a matter of course, any TA study must be available for public use. On the other hand, TA with a focus on intervention in public debates – for example, by organising citizen conferences or setting up lay panels – cannot function without backing from independent scientific expertise, and will be politically meaningless without the involvement of related policymaking bodies.
2.3. Definition, methodology and process of TA

2.3.1. TA definition

Drawing on the brief historical outline given above, TA can be characterised as a hybrid between science and politics. TA is both a scientific endeavour (which delivers data and scientifically proven knowledge and concepts) and a political endeavour designed to prepare decisions that refer to values and interests that lie behind the different perspectives assessing the social or political relevance of scientific data. The general political intention behind TA is to ‘put politics in command’, that is, expand its possibilities of action with regard to the growing dynamics of scientific and technological development. In that respect, TA owes its existence to the perceived lack of knowledge and management capabilities of politics. This weakness of politics with regard to S & T is amplified by a second factor: the lacking or vanishing societal consensus on the objectives of technological development and its compatibility with societal values and needs. Controversies and concrete conflicts about the implementation of new technologies have revealed not only political difficulties in management or planning of technological programmes but also problems regarding the legitimisation of technology-related policy decisions. This description can be further condensed by giving the following definition of TA.
TA embraces the idea of a complex, comprehensive, open and transparent assessment of possible (positive as well as negative) effects of new technological developments in the light of a broad range of scientific branches and perspectives as well as a broad range of values and interests held by different groups in society. In doing so, TA does not pretend to anticipate future developments and reduce uncertainties of decision-making but to support society, politics and science in dealing with uncertainty in a pragmatic, rational and democratic manner.

A TA study usually starts from a particular new technological innovation or advanced scientific procedure in order to look at the social, environmental and economic risks and chances that are connected to them. Looking at ‘impacts’ necessarily also involves taking into account societal conditions that might foster or hinder the implementation and social diffusion of new technologies, in order to come to conclusions on ways to adjust technologies to social needs.

TA, however, may also take a different perspective, and may start from a socially or politically defined problem such as: ‘How to ensure sustainable energy supply’ or ‘How to provide for a powerful but at the same time environmentally sound transport system’. A TA study in this case will explore the opportunities and drawbacks of a broad range of different technologies and compare these with regard to their problem-solving potential, their costs, social acceptability, etc. The main pillars or guiding ideas of TA in both cases can be described as follows:

- comprehensiveness: by taking into account all (sometimes competing) scientific perspectives that might be relevant to the issue at stake as well as all possible effects (environmental, social and economic);
- transparency: with regard to values and normative assumptions that underlie the assessment procedures and with regard to quality of the data and information referred to in the assessment process;
- inclusiveness: with regard to all social interests and values held by social groups that might be affected by new technological developments.

2.3.2. TA methods

TA is focused more on process than application of particular methods. It draws on whatever scientific methods might be appropriate or needed for the study of environmental, social and economic effects of technologies. TA is therefore an interdisciplinary and interactive endeavour that deals with complex issues at the interface between scientific and technological developments and society that are often highly contested among social groups. At the focus of TA is not science and
technology as such but their implications for policymaking. As such, it has to integrate scientific, social and policy analysis. In order to develop options for policymaking in contested S & T areas, a particular mix of competences and methods is needed.

The large spectrum of different interests and values that are involved in debates on science has made ‘participation’ a key issue in the discussion of concepts and methods of TA; that means involving, in one way or another, the perspectives and values of different interest groups in the process of assessing the impacts of new technologies. Involvement of social interests and values through participation is seen as an important factor with respect to several aspects related to the quality of a TA study [Paschen and Petermann, 1991]. Starting from the definition of the problem that has to be dealt with and the identification of relevant questions to be answered, TA needs to be informed by different social perspectives and interests. Moreover, conclusions and in particular recommendations for political decision-making are by no means determined by pure scientific data but are the result of interpretations which depend on different values and different scientific paradigms and theories. Therefore, the process of defining issues and questions to be dealt with in a TA process is in itself a political process that requires involvement of all groups that might be affected by, or have a stake in, the issue under consideration. Apart from the need for a proper representation of the plurality of values in the TA process, participation is seen as a ‘must’ in TA for analytical reasons. The particular knowledge of those affected by technology implementation has to be made available, in order to properly describe the chances and risks connected with the technology at stake and to explore what feasible and innovative solutions there are.

Participation is not only required in order to ensure analytical quality and value representation, but also to ensure acceptability of TA results. Since TA normally acts in a field of highly contested questions and social controversies, such as safety and risks for humans and the environment, it is necessary for TA to analyse questions, perspectives and interests that all groups with a stake in the field can find relevant. TA in this respect intends to contribute to informed rational decision-making by representing and stimulating societal discourse which should help in the end to identify socially acceptable and sound solutions. Thus, a TA process involves scientific as well as interactive methods and procedures [Hennen et al., 2004; Decker and Ladikas, 2004].
TA is not a distinct scientific discipline in itself but a method of applying scientific as well as interactive procedures for rational analysis of S & T consequences, using scientific methods from any scientific branch that is relevant to the issue or problem under consideration. Scientific methods are applied in order to collect data for quantitative and qualitative prediction of possible future developments, to identify economic, social and environmental consequences, or to investigate social values and possible social conflicts. Such methods include:
- Delphi surveys, expert interviews (for gathering multidisciplinary expert knowledge);
- modelling, simulation, systems analysis, material flow analysis (for understanding the socio-technical system);
- trend extrapolation, scenario techniques (for creating knowledge about possible future developments);
- discourse analysis, ethics reviews, value tree analysis (for evaluating and uncovering the argumentative landscape of political and public debates).

Interactive, participatory or dialogue methods are used to organise social interaction in order to explore values, interests and knowledge held by social actors as well as to support conflict management, initialise social learning processes and strengthen the ties between policymaking and the public sphere. Such methods include:
- consensus conferences, citizen juries, focus groups (to bring in the perspective of ordinary citizens);
- stakeholder workshops, focus groups (to explore interests and values held by affected social groups);
- future search conferences, scenario workshops (to allow for joint development of visions and problem-solving among relevant social actors).

These methods are tailored to meet the particular quality criteria that TA procedures have to live up to, such as interdisciplinarity of the research process, scientific reliability of data, transparency and fairness, and relevance of results to policymaking (Decker and Ladikas, 2004; Grunwald, 2002).

2.3.3. TA process

A TA process comprises the exploration of technological features as well as the societal and environmental context of implementation of technologies. TA has to gather and assess scientific data as well as different social values and interests that are relevant to the evaluation of possible consequences in the application of
a technology. An ideal process of a TA study carried out on behalf of a policymaking body (i.e. parliament, governmental department) can be outlined as follows.

Pre-project phase:
- definition of subject by client (policymaking body);
- project outline by the scientific unit;
- discussion on project outline with client and decision on project particulars (main areas of research, most important questions for policymaking, budget) by steering committee, board of advisors.

Project phase:
- setting up a working group (staff with different scientific backgrounds);
- further clarification of questions to be analysed (together with representatives of the client);
- identification of relevant social groups (stakeholders) to be involved;
- collection of information (subcontracts with external experts, stakeholder and expert workshops, interviews, desktop research);
- assessment of technological potential, social context and diffusion of technology, possible impacts;
- outline of the ‘social map’: interests and values held by relevant social groups;
- report on results and outline of policymaking options;
- comments by experts and representatives of stakeholder groups.

Post project phase:
- approval of report by client and publication;
- dissemination of results by scientific unit;
- presentation to client e.g. parliamentary committees;
- consultation on results in policymaking bodies.

Such ideal process in TA studies is not always possible due to time constraints or sensitivities around the particular issue. It is nevertheless apparent that the core framework of interaction with the policymaking bodies and inclusion of a variety of stakeholder perspectives is an integral part of every TA study process. Scientific analysis and bridge-building are both indispensable parts of modern European TA.
2.4. TA as bridge builder between science and society

It is clear from the above that the role modern TA has taken in Europe goes beyond mere S & T analysis and forming of policy options. The interactive aspects of TA are designed to minimise the distance between science and society and, where appropriate, to create ‘bridges’ of understanding between the two. This constitutes an additional and ever-increasing role for TA in its function as science policy advisory which reflects the increasing importance that applied knowledge has in science policymaking.

The use of knowledge in science policymaking has changed over time as a result of changing perspectives of the relationship between scientific knowledge and policymaking. What is called the ‘rationalistic’ concept of scientific knowledge has until recently been the leading view of this relationship. According to this view, science can provide the only rational, in-depth analysis of the problem at stake and, therefore, it is the only legitimate means to explore viable solutions. The policymakers’ function is to study the scientific analysis and incorporate its recommendations in political programmes or legislation. This is a technocratic view of science which equates it with policymaking as it allows for little manoeuvre in deciding the policy outcome of the scientific analysis.

As described in the previous section, this view has been challenged in recent decades for disregarding the incorporation of values and stakeholder interests that is inevitable in any scientific analysis (Torgeson, 1986). The term ‘rational’ analysis is therefore misleading as it insinuates bias-free knowledge which is not the case. Recent studies in the accumulation of scientific knowledge have shown that socio-ethical aspects of S & T developments are not taken into adequate consideration, resulting in incomplete and provisional analysis. For instance, ethical questions on new developments as well as their risk assessment cannot be stripped of stakeholder values and interests which have to be taken into account in subsequent policymaking (Beck, 1985; Funtowicz and Ravetz, 1992). This creates a new reality where ‘fact’ in scientific analysis includes practical aspects of defining the problem through social analysis and even, when necessary, stakeholder negotiation that leads to different policy options. The concepts of ‘post-normal science’ (Funtowicz and Ravetz, 1993) and ‘post-positivistic policymaking process’ (Torgeson, 1986; Héretier, 1993) capture this shift from technocratic to value-ridden scientific knowledge.
The effect of the conceptual shift in knowledge accumulation has initiated many changes in TA functions by promoting its interactive methodologies. At the same time, it has created a new reality in approaching the issue of impact assessment in TA analysis. On the one hand, TA is a technocratic system of providing technical information to policymakers, and, on the other hand, its socio-ethical analysis becomes an integral part of the policy debate that makes it impossible to observe in isolation and on its own merits. Some studies on the utilisation of results of TA by policymakers (e.g. Paschen et al., 1991) show that it is mainly used ‘conceptually’ in providing information on the main issues and direction of debates, but less ‘instrumentally’ in the sense of using its results as guidelines for political action. Such conceptual use might also include: awareness of the complex interconnection of the problem under consideration with different fields of policymaking, possible effects not being taken into account, and change in the policymakers’ view on priorities for political action (Berg et al., 1978).

One could describe two general views as to the restrictions in the application of TA-generated knowledge in policymaking (Hennen et al., 2004).

- Since policymaking is dominated by conflicting interests, values and beliefs, scientific knowledge has to pass through this filter and thus is modified and selected according to interests and opportunities rather than applied according to scientific criteria of rationality. It is more likely for scientific knowledge to be strategically used during processes of negotiation and bargaining according to different interests, values and beliefs.

- Scientific advice often increases complexity of decision-making since it provides a full and unbiased picture of the problem (including different social perspectives and areas of uncertainty). Thus, TA cannot easily be used to foster views held by actors and can almost never provide recipes for problem solving (as often might be expected by policymakers). Instead of direct application of scientific advice, there might be long-term effects on the general perception of problems and practical ways of problem solving. ‘Knowledge, including scientifically-produced knowledge, flows into the decision-making process through obscure channels from many different sources, and this results in a more general awareness of the way the world appears and is structured’ (Albaek, 1995).
2.5. TA functions

Having the above restrictions in mind, we can now turn to an analytical view of the functions of TA in Europe in relation to its impact in policymaking. The definition of ‘impact’ is a complex undertaking as it also refers to the general notion of ‘change’, so far as this is measurable in the overall policymaking context that includes social debates in S & T issues.

Below is a table of TA impact-typology that has been developed collaboratively between parliamentary TA institutes in Europe [3]. Discussions amongst TA practitioners resulted in a unique pan-European consensus on methodological and impact assessment issues in TA (see Hennen et al., 2004).

There are three dimensions of impact that TA is expected to have in society:
- that of raising knowledge about issues among policymakers or in public debates;
- that of forming opinions/attitudes in stakeholders involved in policymaking and/or public debates;
- that of initialising actions taken mainly by policymakers or other relevant actors.

These dimensions of impact are directly linked to issues that TA projects deal with. Three main issue dimensions have been described:
- first, TA delivers information on the technological and scientific aspects of the issue at stake (e.g. technology features, risk assessment, cost-benefit analysis, etc.);
- second, TA describes the societal aspects of the issue (e.g. stakeholder knowledge and values, social conflicts, etc.);
- third, TA analyses the policy aspects of the issue (e.g. legislation, policy options, funding, etc.).

---

3 This collaboration took place under the sponsorship of the European Commission in the project ‘Technology assessment in Europe: between method and impact’ that ran during 2001–03 with the participation of most European Parliamentary Offices of Science and Technology along with a host of European TA institutes.
Table 1: Technology assessment in Europe; a typology of impacts

<table>
<thead>
<tr>
<th>Impact dimension</th>
<th>I. Raising knowledge</th>
<th>II. Forming attitudes/opinions</th>
<th>III. Initialising actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue dimension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technological/</td>
<td>Scientific assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>scientific aspects</td>
<td>a) Technical options assessed and made visible</td>
<td>b) Comprehensive overview on consequences given</td>
<td></td>
</tr>
<tr>
<td>Societal aspects</td>
<td>Social mapping</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>c) Structure of conflicts made transparent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy aspects</td>
<td>Policy analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d) Policy objectives explored</td>
<td>e) Existing policies assessed</td>
<td></td>
</tr>
</tbody>
</table>

The impact dimension in the table can be seen as a continuum in the way TA functions. Whereas ‘raising knowledge’ is a basic and integral function of TA in all institutional contexts found in Europe, the dimension of ‘forming attitudes’ implies an active use of that knowledge in terms of arguments in the debate which could lead to the third dimension of ‘initialising actions’ that is the ultimate impact of the TA process. But if the continuum assumes a hierarchy of impact, from low to high, this should not be seen as a process continuum. It is not a given that TA functions first in raising knowledge, then in raising attitudes and finally in initialising action. On the contrary, TA can have a direct effect in each of the
three dimensions only as part of the design of the particular study and the needs of the target audience.

Let us describe in brief the meaning and content of each impact and issue dimension in the table.

2.5.1. Raising knowledge

The impact dimension of ‘raising knowledge’ is a basic mission of TA and reflects better its technocratic or ‘classic’ aspects. Since its inception in the 1960s, TA has been seen as a means of acquiring reliable scientific information and disseminating it in policymaking circles. Throughout the last decades, this basic function of TA included the acquisition of knowledge not only about hard scientific facts but also regarding the socioeconomic context of technological developments, social conflicts involved in the implementation process and stakeholder-friendly policy options to steer technology development. The particular function of TA in raising the overall awareness of S & T issues is independent of its main outcome [e.g. a technical report or a public debate] or the chosen methodology [e.g. expert workshop or participatory technique]. The impact should be that of creating a new level of understanding of the particular issue at stake.

There are three types of specific impacts that are associated with ‘raising awareness’, as follows.

Scientific assessment

This revolves around two basic functions of TA:

- technical options assessed and made visible: contrasting and comparing different paths of technology development in relation to innovation policies and presenting them to policymakers as a part of detailed information input;
- comprehensive overview of consequences given: undertaking technology foresight analysis in terms of unintended technology risks for health, environment, economy and society. Such analysis usually employs a range of methods from risk assessment to economic modelling and citizen participation.

Social mapping

This refers to analysis of value judgements relating to particular technology developments held by social groups that are influential in the issue. The
function of TA to ‘make the structure of the conflict transparent’ refers to such
analysis that aims at promoting a consensual decision-making process that
should eventually enhance the legitimisation of the final policy. In this way, it pro-
motes a different means of risk analysis: that of assessing values held in stake-
holder analysis and providing opportunities for conflict resolution by bringing out
in the open the parameters of opposing argumentation in the debate. TA provides
such specific knowledge by means of social research (e.g. surveys, discourse
analysis, focus groups, etc.) as well as by participatory methods (e.g. stakeholder
workshops, advisory boards, etc.).

Policy analysis

TA can be regarded as a form of policy analysis so long as it concerns itself with
improving policymaking by analysing the contextual boundaries and opportuni-
ties of policy in a particular issue. Two specific functions are associated with this
type of impact:

- **Policy objectives explored:** exploring policy aspects with regard to their via-
bility, social acceptability and possible side-effects in relevant policy areas.
  In this effort TA attempts to discern applications in terms of their realisability
  within a certain period of time and to explore the degree to which a range of
  social needs can be met by different technological options. A cost-benefit
  analysis of different policy options is also an integral part in this effort.

- **Existing policies assessed:** assessing policies that have already surfaced in
debates on new technologies. Such assessment takes the form of analysing
  the preferences and assumptions which existing policy options are based on
  and the effectiveness of instruments employed to realise them (e.g. legisla-
tion, financial measures, etc.).

2.5.2. Forming attitudes/opinions

After raising knowledge, the next main impact of TA is to influence attitude struc-
tures in the debate. Such a change could take place not only at the level of public
debate but also in smaller debates amongst stakeholder groups or even within
administrative circles. It is nevertheless evident that in order to impact on atti-
tudes and opinions, TA has to take a more open stance in its work and take part
in public discussions, not as a stakeholder but rather as a reliable informer. This
signifies the development of TA from its ‘classic’ form as a technocratic service
to policymakers, to its current form as instigator of public debates. The main
output of the TA process remains the same in both cases, i.e. a written report on
a particular S & T development, but the process of data gathering could vary a lot and the outcome be communicated in different ways to different target groups. There are three main types of impact under the overall heading of ‘Forming attitudes/opinions’, as follows.

**Agenda setting**

TA can impact the agenda of both public and political debates by expanding the perspectives taken into account or by shifting attention to new aspects. More specifically, impact in this area could be seen as:

- **Agenda-setting in political debate**: TA outcomes need to be considered politically either because they evaluate ongoing policymaking processes or because they offer alternatives that are proven to be resonant with relevant stakeholders. Parliamentary TA is particularly well-situated for such impact as it is often asked to aid the political debate, whether by being invited to provide comments during a hearing of a specific parliamentary committee or by providing additional information on a specific issue.

- **Stimulating public debate**: direct or indirect involvement of TA in public debates on S & T developments. TA can be formally requested to aid public debates on controversial issues that require reliable and objective scientific information coupled with thorough analysis of social consequences. Thus, it becomes responsible for setting the agenda of the debate and/or even organising public events. This is particularly evident in the case of new emerging technologies that raise both risk and ethical issues, where instigating public debates amongst stakeholders is necessary to explore possible areas of conflict and hence inform policymakers about the need and options for political intervention. Depending on the potential magnitude of the technology in question, the early stages of technology development might be the appropriate time to stimulate public debates in order to avoid adopting a narrow conceptual framework that underestimates social issues (such as the GM crops debate in Europe).

- **Visions or scenarios introduced to actors**: the use of consensus-building techniques (e.g. Delphi) to explore future long-term developments in S & T that can be used in strategic policymaking. This refers to less established S & T developments that might have multiple socio-economic effects (e.g. sustainable energy production) and offer a range of possibilities for policymaking. The role of TA is to explore alternative paths to policymaking and offer realistic scenarios that might have a direct effect on general views held about the sector.
Mediation

Once S & T developments reach the arena of social debates, creating friction and conflicts, the need for well-balanced analysis is necessary, not only to re-set the agenda of the debate, but also to bring the various parties together in a process of conflict resolution. In such cases, TA might also occasionally be asked to take part in the mediation process. Three specific impacts are associated with the mediation function.

- **Self-reflection among actors**: providing the means for the various actors in the debate to review their perspectives and aims. TA confronts actors with substantive analysis of their arguments (in the light of scientific results and/or social impact analysis) and asks them to re-visit them with a view to changing them in a more socially sustainable manner. Such a process is particularly useful in local or regional conflicts that are not necessarily connected to fundamental value conflicts and thus provide better opportunities for self-reflection and consensual decision-making once an appropriate analysis enters the debate. In cases of highly sensitive debates on ethical aspects of new technologies, TA can also induce self-reflection by setting the arena of discourse in a highly structured procedure that offers equal rights of discussion but restricts communication to substantiated arguments, thus creating high standards of public discourse.

- **Blockade-running**: solving deadlock cases in debates by providing neutral, non-political grounds for dialogue. Stakeholders are sometimes unwilling to pay the high price (in terms of image or power) of compromising their position in the debate. TA as a non-partisan procedure can contribute to blockade-running by bringing in new ideas for problem-solving or a new definition of a problem which may help actors to reframe their position.

- **Bridge-building**: promoting processes that establish mutual trust amongst stakeholders in a technology debate. The issue of trust, or rather the lack of it, has taken centre stage in those modern S & T debates that have become arenas of social conflict. The reasons for the lack of trust in technology controversies are manifold, ranging from mutually exclusive world views to unequal distribution of risks and benefits. TA sometimes contributes to establishing trust by initiating a process of bridge-building. This entails the creation of discussion platforms for actors that are free from external influences and include both expert and non-expert contributions that can provide a comprehensive perspective on the problem at stake.
Restructuring the policy debate

This is a main function of TA in the policy domain as it attempts to offer new policy options by introducing additional analytical knowledge and improving the ability of actors to reflect on vested interests and established perspectives. Three impacts are associated with this function.

- Increased comprehensiveness in policies: increasing the amount of perspectives represented in a particular debate to include all relevant actors. Domination by one particular perspective or group in a debate is a problem not only in terms of fairness but also in terms of sustainability in policymaking. TA functions as a neutral source of analysis and introduction of all relevant actors in the debate. The result is a more comprehensive debate, better evaluation of policy options and better policies fine-tuned with regard to different interests.

- Policies evaluated through debate: building the framework for effective policy debate by increasing comprehensiveness and scrutinising alternative ways of problem-solving. Similar to the previous impact, TA in this case is requested to establish the rules of the debate and introduce the options to be debated. This is particularly useful in regional planning, where policy options require national expertise and analysis of other similar regional situations.

- Democratic legitimisation: enhancing the legitimisation of decision-making by creating the necessary openness and fairness in the process, in other words, promoting the notion of open democratic deliberation. By ensuring that the perspectives of all relevant interest groups have been acknowledged and appropriately scrutinised, the results of the TA-process will enhance the democratic credentials of policymaking.

2.5.3. Initialising action

The impact dimension of ‘initialising action’ represents a key function of TA, albeit the most politically sensitive one. One would expect that TA’s role as policy advisory should lead to concrete policy actions. However, policy action is strictly the remit of policymakers, and TA has no mandate to take part directly in decision-making in the sense of ‘doing politics’. If TA were perceived to prescribe policy actions, this would be considered as illegitimate intervention in the work of policymakers. Therefore, one has to tread carefully when attempting to assess TA’s concrete impact on actions. However, TA is a visible player in the process of decision taking and is also expected to contribute significantly to it. As such, it is legitimate to offer a view as to the ways that TA impacts the final outcome of the policymaking process:
**Reframing the debate**

Debates on new S & T developments can be complex and confusing to non-experts. TA is expected to provide an in-depth analysis of the problem at stake, confirm the credentials of the main arguments and, finally, reduce complexity by showing which policy options are reasonable to opt for. Naturally, there are cases where analysis of the debate might reveal many uncertainties in scientific knowledge and thus increase the complexity of the problem. In such cases, TA’s role is to further scrutinise the problem from a new perspective and establish a more secure ground for decision-making. This can take the form of the following.

- A new action plan or initiative to further scrutinise the problem at stake: namely, initiating a process of revealing dissent and uncertainty about new developments in order to start a comprehensive policy debate. There is often bias in the promotion of new technologies deriving from vested interest that overestimate positive and underestimate negative effects. This is particularly evident in technologies that are at an early, pre-market stage of development. TA is then asked to provide the lead in clarifying the main issues, review the evidence of risk assessment and provide a reliable analysis of options for action. This sometimes leads to specific policy initiatives in relation to the new technology, such as funding R & D programmes on less understood aspects of the technology, setting up expert committees for review of new evidence, requesting public engagement processes, etc.

- A new orientation in established policies: similar but more radical than the previous impact, TA can be instrumental in redefining policy views on new technologies. This is mainly in cases where a technology is very new and its effects not yet foreseeable. TA might initiate re-framing of policy by bringing new definitions and perspectives to the debate. In cases of ongoing discussions on general policy branches (e.g. policy models of sustainable development), TA can bring about reorientation towards new long-term objectives and adoption of new aims and strategies in policymaking.

**New decision-making processes**

This refers to initiatives to restart debates at a new level of inclusion of relevant actors or to apply new procedures of negotiation or bargaining among relevant actors, including the following.

- Introducing new ways of governance: creating new policy processes as a result of a TA process. Activities that incorporate public participation (e.g. consensus conferences, citizen juries, etc.) are used as TA analytical tools but might also
be embedded in specific programmes of new governance. The so-called ‘bottom-up’ approaches to decision-making that are popular in many European countries, where lay people’s views are taken into consideration through a series of public engagement programmes, have been shown through TA projects to be effective tools of S & T policymaking.

- Initiatives to intensify public debate: namely, initiatives to include a broader range of affected interests in the debate or to expand it beyond circles of experts and include moral perspectives and/or perspectives of the general public. This is the case in S & T developments that present high degrees of uncertainty and necessitate socially acceptable decisions. This in turn could require new activities to broaden the debate and include representatives from interest groups that have not been involved in the process of policymaking so far.

**Decision taken**

This represents the final and most direct type of impact but, as above, it should be viewed from a particular perspective in relation to TA. It is a fact that the process from consulting to decision is not a straightforward one and depends on a variety of external influences (e.g. vested interests, lobbying, timing, etc.). Thus, it is almost impossible to de-construct this process in an objective manner to identify the exact location of TA. As such, the specific impacts of TA in this category are highly mediated ones and not directly related to TA’s mission. Nevertheless, it is understood that the general goals of a TA process should include the specific aspect of decision-making, despite the fact that it does not ultimately depend on the TA process itself. Three specific impacts fall under this category.

- Filter of policy alternatives: namely, evaluation of policy alternatives with regard to their practical viability and their economic, social and environmental effects. Such evaluation should support decision-making by leading to conclusions on which policies should be implemented. In the process of evaluation it is imperative that TA avoids politicisation of the issue and maintains maximum transparency and inclusivity of representation.

- New innovation-process implemented: namely, facilitating the introduction of new technologies by inducing appropriate R & D programmes. In this case, TA attempts to balance the needs of society with those of the market in terms of the effects of new S & T developments. Innovation should be both financially viable and socially constructive, and R & D policy requires knowledge about the available spectrum of technological solutions as well as relevant social needs and demands. TA contributes to innovation policy by promoting solutions that are socially sustainable in the long term.
New legislation: namely, turning the results of the advisory process into official regulation. This is the ultimate impact of any process of policy advice as it shows that the solution suggested has indeed been the most comprehensive and pragmatic. Nevertheless, the role of TA is not to create policies but to explore policy options with a view to future legislation. Even when studies focus on the assessment of current legislation, they are not intended to provide a legislative bill. The final bill will almost inevitably be the result of political negotiations that are influenced by external factors other than TA advice. But although it is not easy to demonstrate, TA does sometimes have a direct influence on the final outcome of the legislative process.

2.6. Conclusions: embedding society in S & T policy

It is clear that the interaction between science and society is becoming a cornerstone of S & T policymaking processes in Europe. TA’s expanding roles represent the most vivid reminder that societal values and opinions are becoming well-embedded in the framework of policy. As we have seen, the manner in which this takes place is as diverse as the content of the TA role-description. What is termed ‘societal aspects’ of the ‘issue dimension’ part of the TA role best describes the different ways in which TA analyses the social aspects of S & T developments, but it is by no means exhaustive of the ways in which society interacts with science and policy. Societal aspects permeate all methods of policy advisory and are an indispensable part of all the issues that face S & T policymaking.

One could conclude that it is simply difficult to overestimate the influence that society has in the formation of new S & T programmes. But it is also prudent to remind ourselves that this new reality is still at an experimental level and has not yet reached clear consistency. Science policy and society are still functioning by different rules, and conflicts appear more often than not. Similarly, methodologies that are employed to bring society closer to policy have still not been assessed properly in terms of their actual impact. At the moment, they are still dependent on superficial decisions by political authorities that can change as often as governments do. There is still a long way to go before we can assert that science, society and policy are functioning on a level playing-field and show appropriate respect for each other’s decisions.
The situation in Europe thus offers an exciting opportunity that only social experimentation on such a grand scale can offer. European States have a long history of enlightened thinking that has helped science and technology progress to its current level. At the same time, European publics have shown throughout history their readiness to become involved in current affairs and demand a prominent place in political decision-making. This combination of scientific development and public involvement has come to a crossroad. It is not clear how much science and society are able to work together or how closely their relationship can develop. It is nevertheless clear that their future is common and indivisible. This realisation can only mean a firmer hold by society over how science functions and develops.

References


Science policy advisory in China: structures and social perspectives

Xinghua Zhu
3.1. Introduction

Structures or institutions to advise science and technology policymaking are established in most industrialised countries. Ministries and their departments usually cooperate with a group of advisors from science and industry to develop science and technology (S & T) programmes for different fields of research and development (R & D). Most European countries have established a research council of independent high-level experts who advise governments with regard to upcoming new fields of R & D, setting up new funding programmes as well as developing new public research institutes. Often, national research councils are entitled to evaluate the performance of public research institutions and to give recommendations for their further development. These advisory structures are dedicated to deal with ‘internal matters’ of the national R & D landscape; its nourishment, maintenance and development as a national source of welfare.

According to the widely accepted and cited OECD definition, science and technology policy means the collective measures taken by a government in order to encourage the development of scientific and technical research and to exploit the results for general political objectives. The establishment of science and technology as a national asset, and the direct intervention of governments in the direction and range of R & D activities, marked a new and irreversible turning point in the relations between science and technology and the State in China.

This chapter will focus on policy advisory structures and issues in China. It provides a short review of S & T policymaking in China, discussing its history and transition phases as well as its current status, with particular focus on advisory structures. The process and methodology of S & T advisory in China is addressed through a case study taken from the Chinese Academy of Science and Technology for Development. The chapter concludes with a discussion of the main issues that face S & T policymaking mechanisms in China.

Science and technology policy originated along with the foundation of the People’s Republic of China. As the result of complex political cultural and societal conditions, policymaking in China zigzagged between a traditional Soviet-style policy system and the western model. Since 1978, China’s S & T has undergone significant changes.

China’s political system is not founded on the bases of separation of powers as it is the case with its western counterparts. S & T policies are mainly initiated
and implemented by the executive branch (the State Council as well as its constituent ministries and agencies). The central committees of the Communist Party of China (CPC) and National People’s Congress (NPC) supervise and check the whole process. Hence, to a considerable extent, the State Council is the focus of much interest and attention relating to national S & T administration. NPC, Chinese People’s Political Consultative Conference (CPPCC) and institutions outside the executive branch (including universities, independent research institutes, industrial firms, think tanks, etc.) also play vital roles in the S & T policy process.

From the perspective of science policy mechanisms, China’s governmental R & D system is a combination of a centralist and a pluralist one. Nowadays, about one third of China’s national R & D activities are funded at national and local government level and thus are subject to public S & T policies and procedures. With the establishment of a socialist market system, industrial enterprises now support more than 60% of national R & D activities. The discussion of industry-funded R & D, as well as R & D funded by provincial and local government and other non-governmental institutions, is beyond the scope of this paper. This paper is mainly concerned with policymaking for central government-funded R & D in China.
3.2. Current S & T policymaking in China

The main elements of China’s government S & T system are demonstrated in Figure 1.

Figure 1: The main elements of China central government’s R & D system

3.2.1. The role of the State Council and its constituent ministries

Chinese central government currently invests more than USD 10 billion annually in R & D-related activities. Central government-funded R & D programmes are mainly administered by the agencies of the State Council. This section describes in broad terms how the State Council as well as its constituent ministries and agencies are organised for the conduct of R & D programmes, and how they participate in the formulation and implementation of S & T policy.

Based on the Constitution, the State Council is responsible for the development of China’s science and technology enterprise. In principle, the State Council is structured in a hierarchical manner, with the Premier at the top. But, in practice, the Premier’s substantial power to control the activities of all the agencies is less than absolute because of the sheer size of the government. The Premier exercises a considerable amount of central policymaking authority and policy coordination over the agencies mentioned above through the State Science and Education...
Almost all agencies of the State Council are involved in science and technology, but about 10 ministries and agencies account for the majority of the R & D budget: Ministry of Science and Technology (MOST), National Development and Reform Commission (NDRC), Ministry of Education (MOE), Ministry of Industry and Information Technology (MIIT), National Natural Science Foundation of China (NSFC), Chinese Academy of Science (CAS), etc.

3.2.2. The State Science and Education Steering Group

The State Science and Education Steering Group, founded by the Zhu Rongji administration in 1998, serves as an inter-ministry coordination institution. It is chaired by the Premier of the State Council and co-chaired by a State Councillor, with senior department and agency officials as its members. This steering group is the principal means for the Premier to coordinate science and technology policy across the State Council. For example, to meet new challenges and demands after China’s accession to WTO, and cater to domestic strategic economic restructuring, (with the approval of the 10th session of the State Science and Education Steering Group), MOST organised and implemented more than 10 mega-projects of science research based on the 863 programme and the national key technologies R & D programme. But the influence of the steering group is limited. Most agencies and departments have far better ways of influencing policy process than working through the steering group.

3.2.3. Ministries and agencies of the State Council

There is no unified central government R & D budget process. Each ministry and agency negotiates its overall budget including an R & D budget, with the Ministry of Finance (MOF). Then the budgets are integrated into the whole State Council budget to be approved by the NPC each year. Nominally, the Ministry of Science and Technology (MOST), under the leadership of the Premier, is responsible for the administration of China’s R & D system. MOST makes and promotes national R & D plans (e.g. the 863 programme, 973 programme, key technologies research and development programme, etc.) and is empowered to coordinate its work with other relevant ministries. Several other ministries and agencies, including the Ministry of Agriculture (MOA), Ministry of Education (MOE), National Development and Reform Commission (NDRC), Chinese Academy of Sciences (CAS), Ministry of Industry and Information Technology (MIIT) and the National Natural Science Foundation of China (NSFC), play pivotal roles in national R & D affairs. For example, the NSFC was founded in 1986 for the management of the National
Natural Science Fund, aimed at promoting basic and some applied research in China by financial means. All the ministries and agencies promote R & D related to their missions through their national institutes and through grants to universities and contracts with State-owned or private corporations. Each of the principal R & D related ministries or agencies funds and administers its R & D activities individually with very little inter-agency coordination. For example, NSFC, MOE, and MOST all fund basic research, and duplication of investment cannot be avoided sometimes. Unlike some of its counterparts in developed countries, MOST has no national research institutions in its operating arms, which greatly limits its power as a coordination body due to a lack of relevant expertise.

In China, the largest share of central government-funded R & D activities is carried out by government-owned research institutes and some well-known research universities under grants, with a few activities carried out by industrial firms. As a result the innovative capacities of industrial firms are still low. Contracts are still not widely used except for some applied research and development missions. Universities and CAS are pre-eminent in the area of basic research, performing the majority of the nation’s total.

3.2.4. The role of the National People’s Congress (NPC) and Chinese People’s Political Consultative Conference (CPPCC)

The NPC has the constitutional authority to review and approve the State Council’s annual budget, and superficially has the power of ‘life or death’ over most national R & D activities. However, NPC’s expertise in S & T is very low, and so it plays a less vital role in shaping the national R & D system. Part of the work of NPC is conducted through special committees. The Committees of Education, S & T, Culture and Hygiene are the main institutions with responsibilities for this task. But institutionalised arrangements like that of its counterpart in the United States, as well as in other developed countries, are still absent. The NPC’s influence over R & D in the private sector is less direct, mainly through taxation and regulations.

The CPPCC was established in 1949. It is an important institution of multi-party cooperation and political consultation led by the CPC. It provides the means to promote the system of socialist democracy in China’s political life. The basic structure of China’s political system is the unification of the system of people’s congresses with the system of multi-party cooperation and political consultation, and the system of regional ethnic autonomy, under the leadership of the CPC. The National Committee has several special committees and other
working bodies, for example the Committee of Education, Science, Culture, Health and Sports includes many well-known scientists and intellectuals as members, and plays a pivotal role in influencing S & T policymaking.

3.3. The limited role of some quasi-governmental institutions as advisory bodies

3.3.1. Chinese Academy of Sciences (CAS) and Chinese Academy of Engineering (CAE)

Founded in 1949, CAS is a leading academic institution and comprehensive research and development centre in natural sciences, technological science and high-tech innovation. CAS caters to national strategic demands and promotes original innovation in scientific research and the integration of key technologies, so as to make fundamental, strategic and forward-looking contributions to China’s economic reconstruction, national security and sustainable development. CAS undertakes nationwide integrated surveys on natural resources and the environment, provides scientific data and advice for governmental decision-making, and undertakes government-assigned projects with regard to key S & T problems in the process of social and economic development.

CAE was established in 1994 and offers consultancy to the State on major programmes, planning, guidelines, and policies. With the encouragement of various ministries of the central government as well as local governments, CAE has carried out surveys on the forefront of science, and put forward strategic opinions and proposals on the State’s development strategy, S & T policies and economy, as well as on key issues related to major engineering technologies.

CAS and CAE influence S & T in a number of ways. For example, they provide authoritative advice and policy guidance, sometimes on controversial issues. Their studies and reports bring new issues and problems to the attention of central government agencies, sometimes forcing them to take actions they might not otherwise have taken. They also serve to review and report on progress and needs in disciplines of basic research, and in high technology, as well as in engineering sciences.
3.3.2. Chinese Association for Science and Technology

CAST is a national umbrella organisation composed of various academic and professional societies, which has acted as an important driving force for the development of the nation’s S & T for nearly 50 years. Through uniting China’s S & T personnel to participate in the formulation of policies and regulations on S & T, CAST has made important contributions to the progress of S & T, as well as economic and social development. CAST is now leading its affiliated organisations and members to improve Chinese scientific literacy.

Research universities, trade associations and other organisations also influence policymaking to some extent, but usually behind the scenes through informal measures.

3.4. The development of science and technology policymaking in China

Before the late 1970s, the policymaking and implementation process in China was marked by the language and atmosphere of crisis. In the pre-reform period, confronted with threats first from the USA, then from both the USA and the USSR, China’s R & D centred on defence and heavy industry under a highly centralist system. Following a Soviet Union-styled model, China established a complex R & D system with a large network of government-owned specialised research institutes (mainly under CAS) which carried out the majority of R & D activities, combined with comprehensive and specialist universities. Universities were mainly involved in education and training rather than research. Almost all State-owned enterprises conducted production under the direction of government agencies and few R & D institutes were established within this system. Since 1978, Chinese S & T policy has passed through various phases, responding to changing national development objectives and strategies. The government set up an incremental systemic reform of its S & T system. There are different perspectives about the periodisation of science and technology policymaking in China. A widely accepted and cited one is that the periodisation could be marked by several documents issued by the central committee of CPC and the State Council.
3.4.1. 1985 resolution – all-round reform of science and technology system initiated

In the late 1970s and early 1980s, one of the most important characteristics of China’s S & T development strategy was to promote the import of foreign technology and advanced facilities. During the same period, the Chinese government introduced a reform of its S & T administrative structure. In 1985, the central committee of CPC and the State Council approved the ‘resolution on the reform of the S & T system’. Its main objective was to reform the management of R & D grants and to ease the administration and regulation of research institutes. At the same time, the resolution encouraged universities and applied research institutes to strengthen their links with private enterprises. Soon after this, regulations and laws concerning patent and technology transfer were issued. Industrial policy was directed to expanding technology-intensive industry, such as machinery and electronics.

With the founding of NSFC in 1986 and the subsequent 973 programme, 211 project, and 985 project, universities gradually became significant contributors to basic research and knowledge generation. Nowadays universities account for about 40% of national basic research effort and more than 30% of applied research. In 1988, the first national high-tech development zone was established in Beijing with 52 others soon following; all were supported by the torch programme.

3.4.2. 1995 resolution – to establish a Chinese-style national innovation system

In 1995, the Central Committee of CPC and the State Council issued the ‘resolution on the acceleration of progress in science and technology’. This set the goal for China’s R & D spending to be equivalent to 1.5% of GDP by the year 2000, and called for administrative reforms to meet the needs of the socialist market economy. In general, all the major reform measures from 1995 to around 2000 were directed towards the establishment of a Chinese-style national innovation system (NIS), which was inspired by the NIS literature (Freeman, 1987; Lundvall, 1992; Nelson, 1993) and the successful experiences of some OECD countries. Since 1999, China has begun to transform most government-owned applied research-oriented institutes into private enterprises, or incorporated these into State-owned enterprises, so as to strengthen the innovative capacity of industry firms. Some 242 research institutes once affiliated to the former State Commission for Economy and Trade were transformed into private enterprises by the end of 2001. Inspired by this successful transformation, some 5 000 local
government-owned applied research institutes were also transformed into private enterprises, which strengthened related regional innovation systems. Nowadays, private enterprises account for more than 60% of overall R & D expenditure, a quarter of applied research, and more than 75% of development. As a result, the institutional mechanism for adapting imported technology has been greatly improved. So from the perspective of investment, enterprises have become a vital part of innovation.

China is one of a small number of economies with rapid growth in both R & D expenditure and personnel. During the period 2000–05, the compound annual growth rate (CAGR) of the majority countries in the G7 was less than 3%, while China reported 18.6%. During the same period, the total number of China’s R & D personnel and R & D scientists and engineers went up by 48.0% and 60.9% respectively, while the numbers in most countries either increased slowly or even decreased (MOST, 2006).

With the rapid growth in China’s R & D input over a number of years, the gap in gross S & T input between China and developed countries such as the USA and Japan has narrowed. In 2004, China’s gross R & D expenditure was USD 23.7 billion. China’s ranking improved from ninth in the world in 2000 to sixth in 2004, and its share in the world total R & D expenditure increased from 1.7% in 2000 to 2.7% in 2004. In 2005, China was second in the world in terms of the absolute number of R & D personnel after only the USA. However, there is still a considerable disparity between China’s gross R & D expenditure and key S & T economies. China’s gross R & D expenditure in 2004 was only 1/13 of the US or 1/6 of Japan. It was much lower than 2.25%; the average level of OECD economies. China’s R & D intensity (the ratio of R & D expenditure to GDP) reached 1.34% in 2005, an increase of 0.44%.

In 2005, 86.5% of China’s R & D expenditure, from government funds went to research institutes and higher education institutions that undertook national S & T programmes. Some 11.9% of the government R & D funds were given to the private sector. Of the total number of scientists and engineers engaged in R & D activities in 2005 in China, enterprises accounted for 62.3%, higher education institutions 19.8% and research institutes 15.1%. The general trend is that there is a gradual growth in the share of S & T resources for enterprises and a constant decrease in the share of S & T resources for higher education institutions and research institutes. Compared with advanced economies in the same period, there is no obvious disparity in the share of R & D funds used by enterprises.
The business sector is not only the mainstream investor in R & D activities in China, but also the most important R & D activities performer. In 2005, R & D funds raised by enterprises were CNY 164.3 billion or 67.1% of the total, and R & D activities performed by the private sector have gained financial support of CNY 167.38 billion, or 68.3% of the GERD. The ratio of R & D expenditure performed by enterprises to that of higher education institutions and that of research institutes were 6:2 and 5:1 respectively. China’s research institutes have a similar share to those in Russia, and the share of higher education institutions in China approaches the level of South Korea.

The allocation of S & T resources in China is becoming more optimised, and the gap in R & D expenditure by performing sector between China and most developed countries is becoming smaller. The general distribution of R & D resources in China is becoming increasingly similar to that of OECD countries.

3.4.3. 2006 resolution – building an innovation-oriented country/nation

The Hu Jintao and Wen Jiabao administration is strongly characterised by its recognition of the importance of indigenous innovative capacity. At the Fourth National Conference on Science and Technology, held on 9 January 2006, President Hu and Premier Wen both appealed to push forward reforms in China’s R & D system to build an innovation-oriented country. Premier Wen appealed for better implementation of the national plan for medium and long-term science and technology development. Strategies on how to make innovations should be stipulated and implemented, investment in scientific and technological sections increased and the training of S & T personnel strengthened.

On 9 February 2006, the ‘resolution of the Central Committee of CPC and the State Council on the implementation of the national plan for medium and long-term science and technology development and enhancement of indigenous innovative capacity’, as well as the full text of the plan, was presented to the world. These two documents represent a new milestone of S & T policymaking in China.

The 10th national five-year plan, is the first both in the new century and since China became a member of WTO, and also since President Hu and Prime Minister Wen came to power in 2003. It indicates that the Chinese government will increase R & D expenditure significantly so that indigenous innovative capacity will be greatly strengthened and dependence on foreign technology will be reduced.
In 2005, China’s R & D personnel and expenditure increased by as much as 20%, with an increase of 212,000 person-years over 2004. The total number of R & D scientists and engineers in the same year was equivalent to 1,119,000 person-years, 193,000 person-years more than that in 2004. In 2005, the gross R & D expenditure reached CNY 245 billion in the 10th five-year plan period (2001–05), China’s total number of R & D personnel increased by 443,000 person-years, the compound annual growth rate (CAGR) of R & D personnel was about twice that of the ninth five-year plan period (1996–2000). Similarly, the total R & D expenditure in the 10th five-year plan period was 2.5 times the amount of the ninth five-year plan period.

As to R & D expenditure, two key goals for 2020 are to increase it to 2.5% of GDP (current level is 1.4%) and to quadruple GDP using 2000 as a baseline. The plan intends to strengthen ‘indigenous’ innovation, so as to avoid the dominance of foreign corporations in strategic areas and to avoid high licensing fees. The plan identifies eleven key areas and interrelated priority subjects. The plan also lists 16 key projects to be launched. The need to increase investment in basic research is also emphasised. Following the presentation of the plan, in June 2006, the State Council presented the first batch of 99 supporting policies for the implementation of the plan which clarified the supporting policy assignments, lead departments and leaders.

3.5. S & T advisory: methodology and societal perspectives: the case of Casted

3.5.1. Description: historical evolution of Casted

In the spring of 2006, the first national S & T conference in the new century was held, and the national middle and long-term science and technology development plan outline issued. In the autumn of 2007, the report of the 17th National Communist Party Congress identified proprietary national innovation capacity as the core of the country’s development strategy and the key to comprehensively improving national strengths. To meet the new requirements of the Central Committee of China’s Communist Party and the State Council on S & T and improve the research level of S & T macro development strategies and policies, the Communist Party Committee of the Ministry of Science and Technology (MOST) made a proposal to the State Commission Office for Public Sector Reform to restructure and reform the National Research Center for Science and Technology for
Development (hereinafter referred to as the ‘Research Center’) into a new ‘Chinese Academy of Science and Technology for Development’ (hereinafter referred to as ‘Casted’). On 28 December 2007, Casted was officially established. The President of Casted is Mr Wan Gang, Minister of Science and Technology and Vice-Chairman of the National Committee of the Chinese People’s Political Consultative Conference CPPCC).

The Research Center, the predecessor of Casted, was set up in October 1982, at a time when rapid reforms were opening-up society and economic development in China. Its establishment was approved by the State Council and Mr Deng Xiaoping, the master architect of China’s reforms, inscribed the name for the newly established research center. This should be seen as the beginning of government efforts to establish a systemic advice and consultation system.

The Research Center was a comprehensive soft science research institute directly under MOST. It conducted research on national S & T development strategies, policies, management, foresight, assessment and the role of S & T in facilitating social and economic development. It provided consulting services and suggestions to the macro decision-making level for national S & T, economic and social development.

In the new era, Casted is devoted to facilitating the development of an innovative society, improving proprietary innovation capacity, and conducting forward-looking, holistic and comprehensive strategic research. Casted adheres to the guideline of serving the nation and the S & T cause, and is making great efforts to grow into an international-level S & T development strategic research base, in order to effectively support S & T macro decision-making and management.

The transformation of the Research Center into Casted signals an exciting new journey for this national S & T development strategic research organisation, which is an open and competitive think tank with an international perspective and first-level research capacity.

3.5.2. Functions of Casted

Casted has adopted the organising form of ‘small core, big network’, to set up a project-processing mechanism combining national targets with independent exploration, taking into consideration social needs and realities. Its major functions include the following.
- Participate in the top-level design of national S & T development strategies: under the leadership of the Communist Party Committee of MOST, Casted studies and provides suggestions on the S & T development strategies of China. Casted also conducts research on theoretical innovation, idea innovation and methodological innovation, and plays a guiding and demonstrating role in strategic research for S & T development.

- Conduct and organise research on important strategic issues: following the principles of government-oriented and demand-oriented operation, Casted accepts commissions to conduct key strategic research tasks and provides references and support for national strategic decision-making and policy developments. Casted accepts commissions from central and local government departments, domestic and international enterprises and research organisations, non-governmental organisations and international organisations to conduct research and consulting work.

- Nurture and develop a core S & T strategy talent team: Casted pays great attention to team development, discipline development and local and sector S & T strategic research. Casted also supports explorative research, continuously enriching theoretical systems for S & T development, initialising innovative ideas related to S & T development, and providing decision-making consulting for national S & T strategies and the core work of MOST.

Moreover, Casted attempts to set up an open exchange and communication platform which can integrate the strategic research resources of various parties, create an international and domestic cooperative research network through mechanism innovation, and develop brand periodicals and brand forums.

3.5.3. Case illustrations of policy advisory at Casted

The following cases refer back to the previous chapter that includes the ‘impact matrix’ of technology assessment (Chapter 2, Table 1: Technology assessment in Europe; a typology of impacts). This includes three dimensions of the impact of participation: raising knowledge on issues among policymakers or in the public debate; forming opinions/attitudes of actors involved in policymaking and the debate; and initiating actions taken by policymakers or other actors. There are three dimensions of the issues that technology assessment deals with:

- technological or scientific aspects (features of the technology, results of risk assessment, cost-benefit analysis, eco-balance, etc.).
societal aspects: knowledge about relevant actors (their interests, values, etc.) and the possible conflicts on the technological issues at stake;
- policy aspects: implications for the government (innovation policies, new legislations, etc.).

Hence there are nine possible roles for public or institutional participation in science and technology policy. What is important is to clearly identify the main objectives in any single initiative. The objective will depend on who is the initiator and the characteristics of the problem at stake (e.g. emergent or mature technology, settled interests or not). The key point is that both classic and participatory methodologies will generally open up the issues at stake: it might show that there are more expert controversies than expected, and that there are social and political disagreements on relevant values and objectives. Public deliberation or technical analysis generally reveals the complexity of the problem and the inherent uncertainty of scientific knowledge. Thus, instead of closing down the problem and sorting out what is ‘right’ and ‘wrong’, TA expands the frame of the problem. Indeed, we cannot expect that TA will necessarily accelerate a decision-making process; but it should contribute to making it more robust (based on reliable and legitimate knowledge). In the sections below, we describe how Casted fits into the TA’s ‘impact matrix’ with three examples.

Case 1: National soft science research programme, setting up an open exchange and communication platform

The national soft science research programme is one of the programmes organised and implemented by MOST. The Department of Research Management of Casted was given the responsibility to manage the national soft science research programme and set up an open exchange and communication platform which can integrate the strategic research resources of various parties. The proposals sponsored by the national soft science research programme presented two layers and two ways of communication. Some proposals were initiated by university experts or institutes focusing on national policy issues while other proposals derived from government decision-makers themselves. As a result, the national soft science research programme established an open exchange and stakeholder–communication platform for debates on policy issues that bring in three new aspects of policy advisory, as follows.
1. Consensus implementation
The objective of policymaking is first to achieve consensus among government departments and related stakeholders. Policy advisory helps the implementation stage by reviewing decision-making processes and revisiting the results of the initial consensus. The implementation stage consists of a delicate and sensitive process that brings in additional research and stakeholder opinion that can in turn lead to revisiting the initial consensus.

2. Double-level decision-making model
The policy process takes place simultaneously in the bureaucratic/administrative system and the advisory network. The administrative system functions at the organisational level and defines the formal arena, procedures and rules for policymaking. The advisory network functions at scientific and social levels and identifies social relationships relevant to the issue at stake. As a result, societal analysis is central to the function of the advisory network and reflects the need to expand policymaking into the realm of social debates.

3. Patterns of consensus-achieving
The pattern of consensus-achieving in policymaking is a bottom-up process of discussing opinions on given issues or problems. Similarly, the pattern of science policy advisory is a bottom-up process of analysing opinions driven by the same issues or problems. The inclusion of wider stakeholder opinions gives policy advisory a unique role in exploring S & T issues in full and provide recommendations that are both realistic and achievable.

Overall, the national soft science research programme provided a unique opportunity to expand the role of policy advisory to new areas that are characterised by greater social analysis, wider consultation processes and more sustainable consensus building. The process is still ongoing and is adapting to new ideas and new methodologies that are increasingly appearing in the work within this programme. Although still not on a par with similar communication-based TA methodologies that take place in Europe (as seen on the impact matrix), there are certain similarities that make the consultation aspects of the advisory process compatible in the two regions.
Case 2: Wenchuan rapid assessment survey; participation in the top-level design of national S & T development

A major earthquake measuring 8.0 on the Richter scale hit Wenchuan County of Sichuan province at 14:28:04 on 12 May 2008. Its strength and its catastrophic impact made it among the strongest recorded in the history of China as well as in the world. The Wenchuan earthquake had a shallow hypocenter and high intensity. After the earthquake, tremors were felt in many provinces. Casted’s Institute of Science, Technology and Society initiated the project entitled ‘Post-Wenchuan earthquake rapid needs assessment’. The project gained full support from the Department of Social Development and the Department of International Cooperation of MOST while the leaders of the Planning Group of Post-Wenchuan Earthquake Restoration and Reconstruction under the State Council provided important input in the project.

The project focused on a widespread field survey on the people of the affected province along with a needs assessment study that included infrastructural analysis. About 80 students and teachers from the Mian Yang Normal University and several students and teachers from Sichuan University took on the work of field interviews in very difficult post-earthquake conditions (sponsored by the Ministry of Foreign Affairs of Norway). The main findings of the survey have influenced the reconstruction plans in the affected areas including rebuilding priorities, level of government subsidies, migration policies, employment policies, local human resources organisation, etc.
The project’s success was based on its emphasis on the participation of local people who have been directly affected by the earthquake. The field research and organised discussions with local people helped identify better their immediate needs and the problems they are faced with. As a policy advisory process, the Wenchuan survey represents a direct social needs assessment and participatory methodology that is pioneering in the Chinese context. The following is a schematic overview of the project.

**Figure 3: Rapid response to Wenchuan earthquake: a schematic overview**

- Started pilot in Sichuan earthquake areas
- Started questionnaire design
- June-5
- Started field work
- July-5
- Finished field work, collected information of 4526 households in 24 affected counties
- July-19

**Case 3: Technology foresight: high-tech industries**

At present, China is undergoing rapid economic growth and fast development in high-tech industries; for quite a long period in the future, its economy is projected to maintain such rapid development. However, at the same time, China is faced with the challenges of economic structural adjustment, pressure of international competition, population and employment, restriction of resources, energy and environment, and unbalanced development among different regions. As part of its role to ‘conduct and organise research on important strategic issues’, the Institute of Foresight and Evaluation of Casted was funded by the Department of Development Planning of MOST, to interview about 3000 members of enterprises, universities, institutes, government and foreign experts, in order to produce China’s first report of technology foresight in six fields.
The foresight project involved systematic investigation into science, technology, economy and society, aiming to identify critical developments in the fields of information technologies, biotechnologies, new materials, energy resources and environment, and advanced manufacturing, which are of great significance for China’s social and economic development.

In order to meet the overall target, three tasks had to be completed:

(i) analysis of socioeconomic needs – in accordance with the national strategic aims and the actual national conditions in China, a detailed socioeconomics needs assessment survey was conducted in relation to the six technology fields;

(ii) survey and research on stakeholder opinions – two rounds of Delphi surveys were undertaken with key experts from the six technology fields under review; the results of this widespread consultation were incorporated in the final report as a unique contribution to the foresight process;

(iii) selection of national critical technology – finally, a comprehensive investigation on the technological merits and problems in each of the fields was conducted; this helped to reach an overall conclusion as to the national priorities and identify specific technologies that are critical for the future of the country and its desired socio-economic development.

The success of the foresight project was based in its widespread consultation method and its focus on social needs. As with comparable foresight projects in Europe, the Chinese example provides a good methodological basis for similar processes. For instance, based on the achievements of the technology foresight project, a similar process applied to research on industrial technology road-mapping was undertaken. The road-mapping project promoted governmental management of S & T planning in industrial technologies and is summarised in the graph below [see also Zhu Xinghua and Jiang Yutao, 2008].
3.6. Summary and discussion: S & T policy mechanisms in China, some suggestions for change

The reforms of the 1980s and 1990s have achieved a lot, as the data described in this chapter have shown, but some deep-seated problems still exist in China’s R & D system. The debate in the policy-advisory (TA) community is still ongoing.
as to the best way to tackle the various issues that are creating barriers in its core work. Based on the analysis offered above, three main suggestions for improvement could be made.

1. A State-level coordination mechanism should be established. For instance, a cabinet-level National Science and Technology Council (NSTC) chaired by the Premier or the authorised State Councillor should be established, with ministers from R & D-related departments and experts from academia and industry as its cabinet and executive members. Its role should be to ‘steer’, not to ‘row’. The NSTC should be the principal means within the executive branch to coordinate S & T policy across the diverse entities that make up the national R & D enterprise. The Council could prepare R & D strategies coordinated across national agencies to form investment packages aimed at accomplishing multiple national goals. The work of the NSTC could be organised under several committees. Each of these committees could oversee subcommittees and working groups focused on different aspects of S & T, coordinated across national government.

2. An institutionalised science policy advisory system should be promoted. The role of MOST should be elevated to enhance the coordination of national R & D programmes. It would also serve as secretariat of the NSTC and provide S & T policy services to other ministries. MOST should also establish its own in-house research institutes which will focus on its special missions: according to power and politics organisation theory, expertise is one of the most important bases of an organisation’s social power. It is surprising that institutionalised advisory systems rarely exist in the executive branch agencies, both at the cabinet level and within each ministry and agency. So the administration of R & D and the implementation of S & T policy are almost always subject to the discretion of rigid, bureaucratic systems. In the reforming process, the government has attempted to cope with this problem by establishing a systemic advice and consultation system (in the previous section, a case study on this issue has been described).

3. A high-level National Advisory Council for Science and Technology (NACST) should also be established. A chief science advisor could be appointed by the prime minister whose office could be located in MOST. Each agency with R & D missions should also establish advisory institutions to guide their R & D activities.
To some extent, science and technology mechanisms are one side of a coin, the other side of which is the administrative structure. Briefly speaking, an S & T policy mechanism is the organisational system a government adopts from time to time to coordinate and control research and development activities, which reflect the currently adopted views on the relationship between science, technology and society [Ronayne, 1984]. In the S & T literature, it is widely accepted that there are four types of S & T policy machineries: pluralist, coordination, concerted action and centralist systems. The four systems reflect processes for the coordination of a government’s R & D activities. China’s science policy mechanism resembles that of a centralist system. But because of the nation’s special conditions, a combination of concerted-action science policy mechanism and a centralist one, like that of South Korea, is probably more suitable for China.

In order to construct an innovation-oriented country, China’s R & D system should be deeply reorganised or reinvented, so as to establish effective science and technology machinery. There should be a unified and carefully coordinated R & D budget and a more effective budget accountability system, and governmental regulation should be established, especially for government-funded R & D activities.

Scientists use governmental regulation as an external legitimisation of their practice but, interestingly, most scientists would quite openly admit their ignorance about the details of such regulations. As a result, regulations are like a ‘black box’, the contents of which would only come into play in cases of severe ethical misconduct. Whether misconduct happens or not, however, is not so much guaranteed by government regulations, as by the ethical sensibility of researchers and the values institutionalised in scientific research in general [Felt and Fochler, 2008].

Although the S & T policymaking mechanism of China has gradually converged with that of western developed countries, we cannot simply imitate OECD countries’ S & T policy mechanisms and treat LDCs and OECD countries homogeneously. As a social technology or institutional system, the development of S & T policy is a very complex process. It depends not only on rational adjustment and considerations, but also on more complex social and institutional processes. S & T policy also has to be related to both national contexts and global change. At the same time, the relationship between science, technology and government should be re-examined because of the dramatic impact that S & T has on the environment, energy and social life. Which issues science may govern itself,
and which need to be related to other societal actors, strongly depends on where the boundaries of science and society are assumed to lie (Gieryn, 1995).

It is clear that policymaking patterns must include new forms of public participation. Constructive technology assessment (CTA), which arose during the 1980s in western Europe (Poter, Rossini, Carpenter and Roper, 1980), is a new technological management strategy and tool for policy analysis that we should pay attention to. As a different form from traditional policy analysis, CTA focuses on the practical construction of technology during the whole process of technological development. The characteristics of CTA can be identified in four aspects: multi-subjective, reflexive, dynamic and experimental; and its strategic patterns can be identified as of three kinds: technology forcing, strategic niche management and stimulation and creation of alignment (Xing Huaibin, 2003). The development of CTA in China should concern both technological developments per se and the development of public consciousness and participation in technology developments (Tan yi, Tong Yunhuan, 2007).

As a less developed country, China must construct its S & T policy mechanism and plan its R & D activities more carefully in the new social and institutional setting, so as to make better use of S & T policies to help solve the problems emerging in a rapidly changing world. China should also improve its governance of science and innovation policy according to the prerequisites of wider consultation and participation.

China’s ability to allocate public resources to support government priorities has played a key role in closing the technological gap with the rest of the world. But the design, management and evaluation of programmes could be improved and made more market-oriented and public-friendly. Much still remains to be learned from western counterparts in order to exercise proper checks over the executive branch and achieve high-end programme evaluations. This could entail a long process of institutional and organisational learning. The central government could play a leading role in this process of change by creating better coordination mechanisms across departments and set guidelines to promote more comprehensive policies that are based on social needs assessment and widespread consultation.
Acknowledgements

The author is grateful to Dr Li Wenzhong from the University of Science and Technology of China (USTC), who has participated in Casted research projects and provided material support for sections 2, 3 and 5.

Thanks also to three Casted senior researchers, Wang Fenyu (director of the Department of Research Management), Cheng Jiayu (Director of the Institute of Foresight and Evaluation) and Zhao Yandong (Deputy Director of the Institute of Science, Technology and Society) for material support in the case studies section.

Finally, the author is also thankful for the advice and comments on this chapter from Dr Miltos Ladikas at the Centre for Professional Ethics, University of Central Lancashire, UK.

References


China, Ministry of Science and Technology (2006), China Statistical Yearbook on Science and Technology.


Zhu, Xinghua and Jiang, Yutao (2008), ‘Industrial technology road mapping in Guangdong Province and proposals for governmental management of science and technology planning’, Forum on Science and Technology in China, Vol. 6, pp. 81-84.
4

Dealing with nanoparticles: a comparison between Chinese and European approaches to nanotechnology

Michael Decker and Zhenxing Li
4.1. Introduction

Nanotechnology is considered to be a key technology of the 21st century. Research funding in the sector has increased manifold since the mid-1990s in North America as well as in Europe and Asia. The overall number of patents in the area of nanotechnology in the USA has increased almost exponentially in recent years (The Economist, 2007). At the same time, the crucial aspects of nanotechnology remain rather fuzzy from an outside perspective (4). It is at least unusual that a technology is mainly described by its size or order of magnitude (e.g. $10^{-9}$ m resp. 1 nanometer) and its ‘novelty’ (see Chapter 2).

This novelty refers in most cases to products with new material properties such as increased storage density in electronic devices, scratch-resistant surfaces or tailor-made new materials that allow a simultaneous optimisation of, in principle, opposing properties such as adhesion of tyres and abrasion resistance.

In November 2007, The Economist gave an account of 600 products which producers claim are based on nanotechnology. The best known are probably sun screens using titanium dioxide particles; these particles let visible light pass through while blocking UV light, thus producing transparent ‘sun blocks’. Another example is the widespread usage of nano-size silver particles which have antimicrobial effects in products such as washing machines, bed sheets, soft toys, etc.

There is huge economic potential in nanotechnology applications. This potential has been acknowledged by European policymakers: for example, by the Parliamentary State Secretary of the German Federal Ministry of Education and Research (BMBF), Thomas Rachel, in his opening speech at the EuroNanoForum 2007 in Düsseldorf, Germany (BMBF, 2007). Experts estimate that the total revenue of nanotechnology products will reach up to EUR 1 trillion worldwide in 2015. In addition, nanotechnology is expected to provide new applications in important fields such as climate protection and healthcare (BMBF, 2007).

4 The ‘outside’ perspective refers for example to the perspective of research funding organisations. If they proclaim to fund nanotechnology, they need to decide at a certain point whether or not a particular proposal belongs to nanotechnology. In a similar way a technology assessment needs to narrow down its object in order to identify unintended consequences. In contrast, it is probably less important for an individual researcher in his/her everyday work whether his/her concrete research topic belongs to nanotechnology or not (internal perspective): When he or she wants to apply for research funds it might become relevant in this new context.
The enormous economic potential together with its particularly enabling character make nanotechnology a key technology in all developed countries. As such, nanotechnology has become a good example of a ‘global’ technology. But it has also become global because the risks associated with it, especially the risks referring to nanoparticles, are discussed at global level. Since the first request (by the Canadian ETC Group (2003)) of a moratorium on the production and the use of nanoparticles until their health and environmental effects are better known, a general debate about nanoparticles has ensued. Besides scientific research on the health effects and environmental impact of nanoparticles in order to reduce the uncertainty of the scientific knowledge in this area, a political debate on precautionary measures referring to the production, use and disposal of nanoparticles started. The European Commission developed a strategy “Towards a European strategy for nanotechnology” (COM 2004) taking into account both the chances of nanotechnologies, by focussing on the translation of European excellence in nanosciences into commercially viable products, and the risks, by suggesting guidelines for the safe and responsible development of Nanotechnologies.

In this paper, we compare the European perspectives on dealing with nanoparticles with those of China. We will start with a brief reflection on definitions of nanotechnology and nanoparticles and then describe Chinese and European efforts to deal with nanoparticles. We conclude our findings with an attempt to find a common approach that suits both regions.

4.2. Nanotechnology and nanoparticles: an overview of definitions

The discussion about the definition of nanotechnology is not a new one, and it is still ongoing: ‘To be nano or not to be nano?’ was the question Christian Joachim, Member of the Nanoscience Group at CEMES/CNRS in France, asked in a self-reflecting manner (Joachim, 2005).

The most pragmatic definition to date refers only to its scale:

Nanotechnology: areas of technology where dimensions and tolerances in the range of 0.1–100 nm play a critical role [5].

At the same website the question, ‘What is nano?’, is answered thus:

Nanotechnology describes the creation and utilisation of functional materials, devices and systems with novel functions and properties that are based either on geometrical size or on material-specific peculiarities of nanostructures. Purely geometrically, the prefix ‘nano’ (Greek: dwarf) describes a scale 1 000 times smaller than that of present elements of the micrometer-sphere (1 nm corresponds to the millionth part of a mm). This scale has become accessible both by application of new physical instruments and procedures and by further diminution of present microsystems. Also, structures of an animated and non-animated nature were used as models for self-organising matter.

Here, the length of scale is combined with novelty in functions and properties and is described in both bottom-up and top-down approaches.

The US national nanotechnology initiative states the following in answering the same question:

Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modelling and manipulating matter at this length scale [...] Unusual physical, chemical and biological properties can emerge in materials at the nanoscale. These properties may differ in important ways from the properties of bulk materials and single atoms or molecules [6].

Here, as in the previous definition, the novel functions are due to the smallness in size of the system. The ability to control and manipulate on atomic scale is seen as central to these aspects.

The ‘because of the size’ aspect is also mentioned in the definition by Bachmann:

The object of nanotechnology is the production and application of structures, molecular materials, internal and external surfaces in critical dimensions or production tolerances of some 10 nm to atomic scales. [...] The aim is the preparation of material-dependent properties of solids and their dimensions and new functionalities based on new

7 (Bachmann, 1998, translation MD).
physical-chemical-biological impact principles, caused by the sub-microscopic, respectively the atomic or molecular area. [...] Nanotechnology is dealing with systems with new functions and properties which depend solely on nanoscale effects of their components [7].

This definition adds two new things to our discussion: firstly, the physical-chemical-biological impact principles are mentioned; secondly, the nanoscale effects which cause the new functions and properties are identified. Moreover, material optimisation is also explicitly mentioned here.

The Federal Ministry for Education and Research of Germany (BMBF) defines nanotechnology as follows:

The object of nanotechnology is the production, analysis and application of functional structures whose scales are in the area of below 100 nm. [...] An atom or a molecule does not show the physical properties we are ‘used to’ like electrical conductivity, magnetism, colour, mechanical rigidity or a certain melting point. [...] Nanotechnology takes place in the intermediate area between individual atoms or molecules and larger ensembles of atoms and molecules. In this area, new phenomena appear which cannot be detected on macroscopic objects [8].

This definition focuses on physical properties well known from macroscopic devices, which change at the nanometer level. Moreover, new phenomena which cannot be detected in the macroscopic area are also mentioned.

This difference from the larger-scale behaviour also becomes the central criterion in the definition by the Royal Society of London (Royal Society, 2004) [9]:

Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

The Irish Council for Science, Technology & Innovation (ICSTI) refers generally to the ‘common factor being size’ and becomes more detailed by mentioning the surface to volume ratio and the interaction of light and matter:

Nanotechnology refers to the manipulation of matter on an atomic or near-atomic scale to develop materials and devices with novel properties. Nanotechnology encompasses

---

8 (BMBF, 2002, translation MD).
9 Joachim (2005) reports that the French Academy of Science used the same definition.
a set of technologies and techniques with the potential to be applied across most industrial sectors with the common factor being size. Certain fundamental properties of matter, including melting temperature, electronic properties and colour, alter at the near-atomic scale. Nanoparticles (particles with nanometre-sized dimensions) have a far greater surface area relative to their overall volume as compared with more conventionally-sized particles and consequently interact differently with their physical surroundings. Matter and light also interact differently at the atomic level. These altered properties and phenomena can be exploited to enhance the performance of existing products and components as well to develop completely new innovations and applications’.¹⁰

In China, the definition given by the National Science and Technology Council’s Subcommittee on Nanoscale Science, Engineering and Technology (NSET) in February 2000 is widely accepted. NSET is part of the national nanotechnology initiative of the National Science Foundation in the USA, which defines nanotechnology as:

(i) research and technology development at the atomic, molecular or macro-molecular levels, in the length scale of approximately 1–100 nanometer range;
(ii) creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size;
(iii) the ability to control or manipulate on the atomic scale.

This definition, like most others mentioned above, refers to length scale as well as novel properties and functions which appear at this level of size.

This also occurs in the following definition which is taken into account because it has been developed at the international level by the OECD and also because it refers explicitly to nanoparticles:¹¹

Nanotechnology refers to the systematic manufacturing and/or manipulation of individual nanostructures. In this process it takes advantage of characteristic effects and phenomena of materials/substances that occur in the transition zone between the atomic and mesoscopic scale. These quantum-mechanical and/or elementary-physical effects can open up a spectrum of new characteristics to nanoparticles which larger-scale particles of the same substances do not possess.

In contrast to the definitions presented so far, which tried to elaborate by describing potential distinctions, the European Commission in its communication ‘Towards a European strategy for nanotechnology’ (COM, 2004) focuses explicitly on the collectivity of the term rather than on distinction:

The term ‘nanotechnology’ will be used here as a collective term, encompassing the various branches of nanosciences and nanotechnologies.

Conceptually, nanotechnology refers to science and technology at the nano-scale of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. Such properties can then be observed and exploited at the micro- or macro-scale, for example, for the development of materials and devices with novel functions and performance.

In the code of conduct the following definition is given, which still refers to nanotechnology in a broad sense by using the size as defining element. New is the distinction between naturally occurring and man-made nano-objects (COM 2009, p 13):

Nano-objects: In the absence of recognised international terminology the generic term of ‘nano-object’ is used all throughout the Code of Conduct to designate products resulting from N&N research. It includes nanoparticles and their aggregation at nanoscale, nano-systems, nano-materials, nano-structured materials and nano-products.

N&N research: In the broadest sense understood here, N&N research encompasses all research activities dealing with matter at the nanometric scale (1 to 100 nm). It includes all man-made nano-objects be they engineered or involuntarily generated. Naturally occurring nano-objects are excluded from the scope of the Code of Conduct. N&N research encompasses research activities from the most fundamental research to applied research, technology development and pre and co-normative research underpinning scientific advice, standards and regulations.

With these examples, we have provided an overview of existing definitions from different contexts. The first four derive from the research context, the others from the research funding area. In the economic context, similar or even identical definitions are used. Venture Capital (2002) refers to the definition by the BMBF and adds that a precise definition does not exist and several borderline cases have to be considered.
Besides the considerations referring to the length scale, the aspect of ‘novelty’ is central to most definitions. ‘Completely new innovations and applications’, as mentioned in the definition by the Irish ICSTI, are possible because of the small size and because of the change of physical-chemical-biological properties in this length scale. These descriptions are often supplemented by the statement that these effects or phenomena are not detectable in the macro world.

Another important issue is the role of nanotechnology as an enabling technology. There are only a few ‘original’ nanotechnology products, for example nanoparticles for medical applications. But, in many more cases, a nanotechnology component will be a decisive part of a more complex, usually ‘macro’ product, where the ‘nano’ content might not be identified or recognised easily. These products are and will continue to be increasingly used in a number of fields like energy technology, information and communication technology or biotechnology. To add to the complexity, some of the technology fields mentioned here are integrated into ‘meta-technologies’ like the so-called converging technologies. All of these technological fields are increasingly intertwined and interacting with society.

The lesson learned from these definitions of nanotechnology is that the existing definitions sketch a rather fuzzy picture of what nanotechnology is about. But one can get a ‘feeling’ for the topic, at least after reading several definitions one after another. For the purpose of this paper, we consider ‘nanotechnology’ pragmatically as a heterogeneous set of technologies applied to or using systems at the nanoscale (i.e. with at least one dimension between 1 and 100 nm), where this miniaturisation leads to novel effects or properties that are critical for new products or processes.

4.3. Nanoparticles: between chances and risks, a global perspective

In research and economic policy, nanotechnology is considered as a discipline with revolutionary possibilities for innovation in various fields of application and as one of the most important emergent technologies of the 21st century. In parallel to its booming research development, a debate on the risks of the related developments has emerged in scientific circles, the media and amongst the interested public (particularly within environmental groups and economy-related NGOs) (e.g. ITA, 2006; Schmid et al., 2006; EGE 2007; Fleischer and Grunwald, 2008).
From the viewpoint of technology assessment, three different lines of discussion can be observed (with different dimensions of consequences and time horizons):

(i) the potential emergence of ‘risks’ caused by unknown characteristics of nanomaterials (particularly synthetic nanoparticles) and their effects on humans and the environment;

(ii) impacts of ‘enabling innovations’ in fields of technology that are not part of nanotechnology themselves, but which cannot be realised in this form without nanotechnological contributions – this applies, among others, to information and communication technologies and their visions of embedding and ubiquity, or to medical technologies with new ways of technical implementation of findings at the interface between nano-, bio-, information and cognitive sciences;

(iii) nanotechnology as another example of ‘risk technologies’ in debates on general questions of societal regulation of science, trust in science, scientists and their sponsors as well as societal influence on research and technology policy – the way society deals with the (potential) risks of the growing technological use of these specifically manufactured synthetic nanoparticles has emerged as an important issue in the debates on the governance of nanotechnology (see for example COM 2005; Renn/Roco, 2006; Meili et al, 2007).

The economic attractiveness of these particles is primarily based on the fact that they show characteristics which larger structures of the same material do not possess. If this is true for the physical-chemical characteristics, it seems plausible that this may also apply to their biological and toxic properties. Are toxicological evaluations carried out for bulk materials also valid for nanoscale particles? Will such particles be absorbed differently into the human body and what are their effects on health? Will they be transported within the body, will they be excreted or do they accumulate? Do they have harmful effects? These questions are not only relevant to scientists, but also to politicians and regulatory authorities, non-governmental organisations and the media (Helland, et al., 2006; Siegrist et al., 2007).

Those stakeholders who would like to state a well-founded position face a number of challenges. At present, there are not enough results of toxicological research on nanoparticles. In addition, the studies are often methodologically criticised, which leads to problems of validation. The viewpoints of experts often differ greatly with regard to the interpretation of research results, whereas the media seem to concentrate on those opinions that emphasise the risk elements.
From the perspective of materials development, it is important that nanoscale particles can be manufactured from many different materials and may also be combined or coated with other substances. This large variety can hardly be examined in every single case, so the question arises whether research results for one group of materials can be transferred to other groups of materials (Krug/Fleischer, 2007; Helland et al., 2007).

Obviously the aspects of scientific-technological risks (i) and nanotechnology as representative of ‘general risk technologies’ (iii) are interconnected. The precautionary principle is one of the ways to deal with this special constellation. On the one hand, the application of nanoparticles provides huge scientific-technological opportunities in many areas, but, on the other hand, according to today’s state of knowledge, it is yet unclear which risks nanoparticles represent to humans and the environment. The precautionary principle is already established at a global level. In the so-called Rio Declaration on Environment and Development (UNCED, 1992; BMU, 1992) the precautionary approach was agreed as one of the principles that regulate the rights and obligations of nation States. Principle 15 states:

*In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The precautionary principle is also laid down in the international (i.e. European) jurisdiction [12]. The Court of Justice, for instance, when it had to judge on the validity of the European Commission’s decision to ban the export of beef from the United Kingdom to limit the risk of transmission of BSE, held the following opinion:

*Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.* (5 May 1998, Decisions in cases C-157/96 and C-180/96).

---

12 A more detailed description can be found in COM2000[1]: 9ff, as well as in its appendices I and II.
4.4. China’s views on nanoparticles

As in most industrialised countries, programmes and initiatives on nanotechnology started in the 1980s in China. To date, several centres for research and development of nanoscience and technology have been established in the Chinese Academy of Sciences (CAS), at Peking University, Tsinghua University, Nanjing University, East China University of Science and Technology, Shanghai and Tianjing cities, etc. More than 120 research organisations are engaged in the research and development of nanoscience and nanotechnology. In 2002, China established the National Centre for Nanoscience and Technology (NCNST). To effectively exploit the potential of the nanotechnological facilities, NCNST established a unique operating structure which consists of core labs at the centre and coordination labs distributed between different universities and public institutions. NCNST provides a technology platform for domestic researchers from research institutions and industries, and a communication window for international linkage or collaboration on nanotechnology (Bai Chunli, 2005; NCNST website).

Recently, Kostoff et al. (2006) analysed the global distribution of nanotechnology research based on the Science Citation Index (SCI) literature. They reported that the far eastern countries have expanded their nanotechnology publication output dramatically in the past decade. China ranks second to the USA in nanotechnology papers published in the SCI, and has increased its nanotechnology publication output by a factor of 21 in a decade. From the viewpoint of SCI papers, one sees that the active research system in China has promoted a rapid development of nanosciences in the country. Nevertheless, there have been considerably fewer nanotechnology patents granted in China than in most developed countries. Most Chinese scientists remain at the level of preparing novel materials for nanoscale devices, as well as at the level of investigating new physical phenomena. The investigations on the designed devices, structure, functions, mechanism, etc. of the nanoscale are still relatively weak, as compared with the levels in the USA, EU, etc. China is ready to increase funding into this field in order to achieve progress above the present levels, and also encourage international collaboration (Bai Chunli, 2005; Zhao et al., 2007).

According to comments by the NCNST, the focus areas of China’s nanotech commercialisation can be identified as:

- nanomaterials: composite, self-cleaning, multifunctional powder;
- nanodevices: sensors, healthcare detectors, storage and display;
- nanobiology: DNA and protein chips, traditional Chinese medicine, tools for early diagnosis.
From a political perspective, the Chinese Ministry of Science and Technology convened a working meeting on nanotechnology in 2003, where it advanced three goals for nanotechnology development for 2010.

1. The cutting-edge of nanotechnology research should focus on nano-electronics, nano-scale processing and manufacturing, nano-biology and nano-medicine, and nano-materials. A world-class, open-to-the-public nanotech exhibition centre and keystone nanotech laboratory should be established. The nanotechnology information network should also be strengthened and expanded while a national nanotechnology innovation system should be established.

2. The continued development and application of nanotechnology requires overcoming a series of key technological barriers. It is critical to acquire intellectual property rights with regard to the fields of nano-material preparation, nano-device manufacture, microcomputers and information systems, environment and energy sources, medical and sanitation, biology and agriculture, space-flight and aviation, and national defence. These fields lay the technological foundation for the application and industrialisation of nanotechnology research.

3. Attract experts in multiple fields to study and develop nanotechnology to form the backbone of the industry. Foster and invite competent personnel simultaneously versed in technology and business, who will strengthen the industrialisation of nanotechnology.

4.4.1. Precautionary action in Chinese policymaking

With the rapid development of nanosciences and nanotechnology, diverse types of manufactured nanomaterials have been utilised in many consumer products to improve the performance of their core functions, or also to create completely novel functions, such as industrial products, semiconductors, electronics, stain-resistant clothing, ski wax, catalysts, and other commodities such as food, sunscreens, cosmetics, automobile parts, etc. They are also increasingly utilised in medicines for purposes of clinic therapy, diagnosis and drug delivery. However, these ‘positive functions’ need to be balanced with the potential risks. Recent studies on the biological impacts of nanomaterials show signs that some nanoparticles exhibit unforeseen toxicity to living organisms, and may become potentially harmful to human health. Accordingly, questions about the safe development of nanotechnology should be dealt with. This has already become a big challenge for both scientists and governments worldwide. Precautionary actions that govern nanotechnology development have been initiated in China as follows.
(a) The risks associated with nanotechnology developments are discussed
The Xiangshan Science Conference (No 314) took place on 27–29 November 2007 around the topic ‘Nanotechnology and environmental safety’. About 40 participants, including nanotechnology specialists and government officers, gathered to discuss issues such as:
- the environmental risks and safety identification of nanomaterials;
- nanotechnology and its utilisation for environmental improvement and recovery;
- identification of nanoparticles.

All the participants suggested that safety issues of nanotechnology require more attention. This should entail debates with more stakeholders including not only experts and government officers, but also citizens and entrepreneurs. With such discussion platforms, the risks of nanotechnology can be better recognised, so as to assure the rapid and safe development of nanotechnology.

(b) Funding on nanotechnology safety studies has been increased
China has supported nanotechnology projects in its national programmes, such as the national basic research programme (973) and the national high-tech programme (863). Moreover, it is evident that funding should increase as the importance of developing nanotechnology in a safe way becomes a central research goal. We suggest that special funds should be set up to support studies on safety of nanotechnology such as, for example, the following project in the ‘973’ programme [13].

China has established the Laboratory for Bio-Environmental Health Sciences of Nanoscale Materials, where scientists conduct multidisciplinary studies on the biological effects of nanomaterials. This includes the identification and quantification of hazards resulting from exposure to nanomaterials, as well as public health aspects of nanoparticles in air, water, other parts of the environment, foods and nanodrugs. The project assimilates knowledge and techniques from a series of disciplines including nanoscience, toxicology, medicine, life sciences, chemistry and physics. The objective of the project is to meet the national demands of development of the whole nanotechnology field by selecting typical nanomaterials (that have a large-scale production in China) as research objects. The project systematically studies the interactions of nanoparticles with biological systems from diverse levels including the bio-molecular, cellular, organ, and whole body levels, in order to reveal the commonalities of their interactions and

13 http://7056.973program.org
consequences, develop the prediction model for biological effects of nanomaterials, explore solutions to nanosafety issues, etc.

The project mainly aims to address the following key issues:
- the ability of nanoparticles to break through biological defence systems, interactions between nanoparticles and biological barriers, and the paths through which nanoparticles can enter the human body;
- what nanoparticles do after entering the human body, i.e., their biological activities in vivo;
- ADME and toxicity of nanoparticles in vivo;
- the relationship between nanotoxicity and nanosised characterisations;
- modelling for prediction of biological safety of nanomaterials, etc.

The project includes seven research themes:
- nanoparticles breaking through biological barriers;
- the biological activities, ADME-Tox, and target organ selectivity of nanoparticles;
- the cellular nanotoxicity and target cell selectivity of nanoparticles, and their nano-character dependence;
- the molecular nanotoxicity and target molecule selectivity of nanoparticles, and their nano-character dependence;
- innovative methodologies for nanotoxicological studies;
- solutions for nanosafety issues;
- developing a nanosafety database and nanosafety modelling.

(c) Standards for nanotechnology have been established
In order to deal with the risks of nanotechnology, standards of nanotechnology and nanomaterials were introduced by the Committee of National Nanotechnology Standards in April 2005. China has published 15 nanotechnology standards including 11 at national level and four especially for industry. These standards should be developed in more detail in order to meet the needs of the rapid industrial development of nanotechnology. A classification system should also be set up according to which systems of nanotechnology can be categorised (14).

4.4.2. Nanotechnology safety: suggestions for improvement

What can we do to govern the development and utilisation of nanotechnology in an appropriate way? This is a question common to the USA, EU and China, who lead the development of nanotechnology. In China, many actions that deal with
nanotechnology risks have been initiated, but there is still a lot to be done to improve the level of protection. Nanotechnology risks are not only to be found at the level of scientific development but also in its social and ethical aspects. In addition to questions on nanotechnology effects on human health and the environment, it is imperative to think about the social and ethical issues that the technology raises. Questions such as, ‘What is the impact of nanotechnology on traditional ethics and culture?’, ‘What is public opinion on these developments, in terms of fears and hopes?’, ‘What tools can we use to regulate developments?’, should be addressed. We suggest the following steps.

(a) Government support for safety studies should be increased
The development of nanotechnology should be based on knowledge about possible risks, therefore studies on risk aspects of nanoparticles should be promoted and the relevant funding should be increased. We suggest that more projects be set up that focus both on basic safety studies of nanoparticles in the human body and the environment, and on how best to identify nanoparticles and evaluate risks in their production.

(b) Social and ethical evaluation should be enhanced
As has been the case with other technologies, such as genetically modified mechanisms, fast development of nanotechnology could create a series of social and ethical problems. Such problems derive from lack of knowledge of nanomaterials’ character and toxicity (15). For instance, nanotechnology could aid in the reproduction of human beings and also provide the ability to alter human genetic make-up. This creates many issues that should be dealt with at community level and not left to individual choices.

Nanotechnology application may also involve environmental ethical issues. For instance, industrialisation of production without adequate environmental and safety evaluations could lead to environmental pollution and threats to biodiversity systems on the microcosmic level and creation of irreversible damage, thus breaching the environmental ethical principle of equity between generations. Similarly, nanotechnology applications in the military could create a new round of the arms race and further possibilities for use by terrorist groups.

14 http://www.edu.cn/cheng_guo_zhan_shi_1085/20070612/t20070612_237526.shtml
Besides these issues, nanotechnology applications could bring some new ethical considerations. For instance, human capabilities enhancement through nanoparticles could create unfair competition amongst athletes but also among the general population. For these reasons, we suggest that studies on social and ethical problems in nanotechnologies should be funded, and social scientists should be involved in the process of decision-making in nanotechnology developments within national programmes such as the ‘973’.

(c) A viable nanotechnology regulation and governance system should be set up
China has taken many precautionary actions to regulate and govern nanotechnology developments but it is still necessary to set up a viable system based on the precautionary principle. Laws, regulations, technology standards and public opinion should play a vital part in this system, so as to ensure that nanotechnology develops in an appropriate way.

(d) Cooperation with other countries should be strengthened
The risks of nanotechnology pose a challenge to all countries in the world. The USA and Europe have made good progress in this field and China has taken part in various international collaborations with these countries. Since research in the field of social and ethical evaluation of nanotechnology developments in China is not as advanced as in the USA and Europe, cooperation is important to avoid making similar mistakes and to promote the smooth development of nanotechnology.

4.5. European approaches to nanotechnology issues
Arie Rip sees nanotechnology as a ‘field of tension between fiction and precaution’ (Rip, 2006). Regarding nanoparticles, he comments that – due to the discussions on related risks – they are a phenomenon that suggests the application of the precautionary principle. This view is shared across Europe to a large extent. The UK’s Royal Society explicitly recommends the application of the precautionary principle as a regulatory action (Royal Society, 2004). The arguments in the UK White Paper on nanotechnology risk governance are very similar, although without the explicit reference to the precautionary principle (Renn and Roco, 2006). Renn and Roco distinguish between two risk areas in nanotechnology: the passive nanostructures, of which nanoparticles are a part, and active nanostructures and nanosystems. The measures suggested for the first group aim at precautionary action, with the main issue being how much precaution is necessary.
To avoid conflicts, the International Risk Governance Council of Switzerland therefore advises policy to verify the following question, based on the White Paper (IRGC, 2007, p. 25).

Can potential conflicts between advocates of and opponents to nanotechnology be managed? How much precaution in the development, regulation and use of nanomaterials is necessary to achieve an optimal balance between technological progress and effective and transparent risk management?

In a study conducted by the Europäische Akademie zur Erforschung von Folgen wissenschaftlich-technischer Entwicklungen, in Germany, a precautionary approach is also described as a practicable strategy for the risk management of nanoparticle handling. This recommendation is based on the idea that the precautionary principle was specifically developed to allow for a more flexible, case-specific proceeding as proposed by Hans Jonas in The imperative of responsibility (Das Prinzip Verantwortung, 1979). He suggested that, according to a heuristics of fear, a negative forecast should be prioritised and thus – if in doubt – actions or new technologies should be prohibited. The Institut für ökologische Wirtschaftsforschung in Germany also reasoned that a strategy guided by precaution is appropriate in the context of nanoparticles (Haum et al., 2004). Since 2004 the precautionary approach is also central in the European strategy to deal with risks related to nanotechnologies in general and nanoparticles in particular (COM 2005, COM 2009).

Based on the widespread agreement to apply the precautionary principle to nanoparticles, we will now analyse in more detail how this decision can be formally justified and which level of protection can be regarded as adequate in Europe.

4.5.1. Precautionary action in perspective

The starting point for the operationalisation of the precautionary principle (16) should either be existing rules and standards, for example the directive of the European Parliament on genetically modified organisms (GMO) (EU, 2001), according to which the precautionary approach is applied, or a political decision. The political decision of whether the precautionary principle should be applied in a certain field, e. g. climate protection, the protection of the ozone layer or,  

16 The presentation of the individual steps of operationalisation follows the suggestion of René von Schomberg (2006) an application to nanotechnology can be found in Decker (2008).
as in this case, nanomaterial handling aims at justifying immediate action without referring to a sound knowledge base. In this sense, the European Commission is right in pointing out that this fundamental decision was the first step towards risk management (COM [2000], 13f), no matter what the final decision will be. Also the decision not to act (at first), i.e. not to apply the precautionary principle, constitutes the starting point of risk management, assuming that the decision taken was well-founded. The justification should consider three aspects:

(i) possible negative effects;
(ii) the scientific assessment of these effects;
(iii) the evaluation of the scientific uncertainty of this knowledge.

According to these three steps, the identification of possible (side) effects can be established. Several studies on this topic have been conducted. While the penetration of nanoparticles through the skin has to date not been proven (for more details see Butz 2008), incorporation through the lungs is deemed to be much more likely. According to Krug et al. (2008) the inhalation of nanoparticles and the overcoming of the air-blood barrier in the lungs are the decisive path for a risk analysis. Nanoparticles incorporated in this way were found in many different organs in animal experiments, including the brain. The permeation via the nasal mucosa by intake of breath may also be possible. So the ‘effect’ of a potential penetration of nanoparticles into the human body needs to be assessed.

The second step in the decision-making process, i.e. the scientific assessment of effects, cannot be performed completely; it is not clearly proven what kind of effects nanoparticles have in the body. On the one hand, they are too small to be recognised as invaders by the leucocytes of the body and, on the other hand, scientific research of toxic impacts is still in its early stages. Furthermore, the novelty of the physical, chemical and biological characteristics which are attributable to the small size of the nanoparticles is exactly what nanotechnology wants to take advantage of. But regarding the possible toxicity of the particles, this is the main problem: findings on individual substances, i.e. their qualification according to existing standards like the Chemical Acts, cannot be transferred to nanoscale particles of the same substance. However, it is not known in advance at which particle size a new characteristic emerges, which might be accompanied by a change in toxic properties. This means that a statement like: ‘this substance is also non-toxic in nanometre scale’ can only be made after thorough tests of particles of different sizes of the same substance. Toxicological research is therefore confronted with the major task of performing a multitude of tests for every substance that could be applied in the nanoscale. If it is also taken into
account that toxic impacts can occur in different ways (oxidative stress, cytotoxicity etc.), the number of tests that have to be performed can be enormous. It can be stated that toxicological research is facing a vast research assignment, which has only just begun – albeit worldwide and on a large scale.

The third step is related to the assessment of the uncertainty of knowledge. When the status quo studied in the second step is described in this respect, the ‘non-knowledge’ regarding the substances which have not yet been toxicologically assessed could also apply here. In addition, there are also methodological uncertainties which are typical for any science in a new field of application. For instance, well-established toxicological research methods have been optimised for the macroscopic field and nanoparticles with their new – and to some extent unexpected – properties pose a methodological challenge. Some proven tests have reached the limits of their applicability; others might remain applicable, probably with some modifications; and new tests will have to be developed. Harald Krug et al. (2008, p. 70) report on a case study that showed elevated toxicity levels that were found to have been caused by a solvent rather than the substance under examination. It has to be pointed out that this was not poor scientific work but the result of the effort to optimise a traditional scientific methodology towards a new field of application, namely nanoparticles.

The focus of this discussion so far has been on the assessment of the potential toxic effects of nanoparticles on humans and animals. If this perspective is extended to environmental effects in general, the uncertainty of knowledge and also the ‘known non-knowledge’ will increase further. Harald Krug refers to Oberdörster et al. (2005, Figure 5, p. 828) and mentions several ways that nanoparticles can diffuse between the different compartments in the environment. The black dashed lines are relevant here for assessing the uncertainty of knowledge. This is about paths that have not yet been studied or proven but are plausible enough to be worth investigation. So they contribute to the uncertainty of the status quo of knowledge. If nanoparticles were released into the environment during the manufacturing, or use, or after the disposal of products, there is very little information about the way they would ‘behave’.

To sum up, it can be stated that there are concrete indicators for the toxicity of nanoparticles regarding their (side) effects, and that the evaluation of the currently available knowledge has several gaps because of the enormous number of ‘cases’ under investigation. Therefore considerable uncertainty concerning this knowledge exists. The fact that it has not yet been investigated how nanoparticles can ‘move’
in the environment adds another ‘dimension of uncertainty’. This constellation of first scientific indications for concrete effects with the incomplete status quo of research which also features some uncertainties, can be seen as a basis for the application of the precautionary principle.

4.5.2. The level of required protection

In the 2002 Treaty establishing the European Community, Article 174 explicitly mentions precaution in the context of environmental policy:

(2) Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle...

According to Rene von Schomberg [2006, p. 25], the political-legal framework thus predetermines the direction of the debate favoured by the EU with the remark that a high level of protection is intended. The general level of protection is becoming a reference point in the discussion on whether or not the precautionary principle should be applied for a specific phenomenon. Proponents claim that the application of the precautionary principle has to prove that the level of protection is violated while opponents try to demonstrate with their arguments that the politically intended level of protection is being met. Every State is explicitly authorised by international agreements (e.g. WTO treaties) to determine its own level of protection. Sovereignty of the States in this matter should enable their decision-makers to account for the economic situation of the State and its socio-political priorities when they define the required level of protection. In this sense, an international agreement to apply the precautionary principle does not include concrete standards like, for example, the application of particular environmental or health regulations.

Nevertheless, international agreements on the application of the precautionary principle include a normative force that is fed by a claim for consistency. If a State has decided on a certain level of protection – taking into account its economic situation and socio-political priorities – it determines its own standards that cannot be influenced from the ‘outside’ (e.g. the EU). So the EU could request that, for reasons of consistency, a State which has already decided on a high level of protection in respect of one area, applies the same level of protection, to the current case. The choice of the level of protection is linked to the question ‘Which risk is acceptable for a society?’, and is intrinsically tied to the level of risk that
is deemed to be reasonable for the citizens. The political controversy is then based on the possible discrepancy between the level of risk that was considered as reasonable by politicians and the actual level of risk that the citizens would be willing to accept in certain contexts.

The political debate on the adequate level of protection for nanoparticles was started by the ETC Group (2003). They requested a moratorium on the manufacturing of nanoparticles until their innocuousness was proven. This suggestion was geared to the heuristics of fear, which means refraining from actions with unclear consequences. In contrast, other surveys came to the conclusion that precaution may indeed be necessary, but that the evidence found so far could hardly justify such a strict decision, i.e. the ban of nanoparticles. Several studies came to similar conclusions, each of them discussing the suggestion of a moratorium by the ETC Group (Brune et al., 2004; Royal Society, 2004; Haum et al., 2004):

Taking into account our present-day knowledge, there is, with regard to nanospecific effects [excluding self-organisation effects and cumulative effects of mass production], no reason for particular great concern about global and irreversible effects of a specific technology ‘per se’, with it being on par with the justifiable apprehension concerning nuclear technology and genetic engineering.’ Haum (2004, p. 16)

Haum refers to the determination of the level of protection: the same level of protection that has been applied in nuclear technology and genetic engineering. Since these are suggestions by analogy, another suggestion should be mentioned here as well, although in this case scientific evidence led to a strict ban. The comparison of the shape of some nanoparticles (e.g. nanotubes) with some asbestos fibres can often be found in discussions (Brune et al., 2004; Royal Society, 2004; Renn and Roco, 2006), always with the remark that such a potential catastrophe (Gee and Greenberg, 2002) has to be prevented (17). If we bring to mind the normative force of the determination of the level of protection, the current status of discussion can be summarised in the overall recommendation that a high level of protection should be aspired to for nanoparticle handling. The current state of knowledge suggests that some nanoparticles (e.g. nanotubes) are considered to have the potential to ‘violate’ this level of protection, but the results of the surveys conducted so far cannot be used to justify a ban of nanoparticles.

17 The first toxicological experiments on nanotubes have been performed and to date no effects have been proven that could be compared with those caused by asbestos fibres.
Accompanying this scientific discourse and deeply cross-correlated with it is the initiative of the European Commission that started in 2004 with a discussion process\(^{18}\) included in the Communication “Towards a European strategy for nanotechnology” (COM 2004). An integral part of this process was a widespread public consultation exercise and the ethical reflection by the European Group on Ethics in Science and new Technologies (EGE 2007). In 2008 the European Commission formulated a recommendation on a code of conduct for responsible nanosciences and nanotechnologies research [COM 2009] that refers to precaution as one of the general principles the code of conduct is based on. With the publication of the code the European Commissions arrives at a preliminary conclusion by recommending “that the member states encourage the voluntary adoption of the Code of Conduct by relevant national and regional authorities, employers and research funding bodies and any individual or civil society organisation involved or interested in nanotechnology research […]” [COM 2009, recommendation 4].

In this manner, the code of conduct can be interpreted as structuring the direction of the debate (see above) that is favoured by the European Commission whereas the Member States are asked to follow “the principles and guidelines [of the code [remark by the authors]] when implementing their national regulatory research and development strategies [...]” [COM 2009, recommendation 2]. In fact the code of conduct, in combination with the Council Conclusions on Responsible nanosciences and nanotechnologies research [COM 2009], constitutes a policy decision to initiate actions according to the precautionary principle while Member States are requested to introduce adequate measures with reference to their protection level. The debate in the Member states has already started (for example in Germany [NanoKommission 2008] and the UK [ResponsibleNanoCode\(^{19}\)]).

4.6. Concluding remarks

Having described the discussion in Europe and China separately, we will now consider the assessment of a possible joint framework for regulation. The strong requests for standardisation in China and the statements on the precautionary principle in Europe culminating in the code of conduct [COM 2009] can be interpreted in this way. Two different lines of argument lead us to the conclusion that it should be possible to promote the opportunities of nanotechnology (and

\(^{18}\) A comprehensive description of the process can be found in COM (2009) p 10f.
\(^{19}\) www.responsiblenanocode.org, update May 2008.
especially nanoparticles), but that there should also be regulation of the use of nanoparticles as long as the knowledge of their side effects is still very vague. We will therefore try to answer the question of what such a framework of regulation could look like and which concrete measures could be taken.

- The framework of regulation

How such a framework of regulation could look like shall be discussed with the example of REACH\(^\text{20}\). Chemical substances in general are regulated by concrete licensing procedures. In December 2006 – after seven years of negotiations – the European Union came to a final conclusion that constitutes a Europe-wide basis for the licensing of chemical substances. This regulation was published under the acronym REACH\(^\text{21}\). The registration of new substances is a crucial aspect of the REACH regulation. In the future, substances as such, but also mixtures and articles, can only be manufactured in or imported into the European Union if they have been registered according to the terms of this regulation. An inventory has to be established for every substance in the framework of this registration, specifying the different physical-chemical data as well as toxicological and ecotoxicological information. The extent of the required information depends on the quantity which the applicant manufactures or imports of this substance per year. This regulation of ‘ordinary’ chemicals is complemented by a special licensing procedure for the use of substances of very high concern (SVHC) (e.g. carcinogenic, mutagenic, reprotoxic or persistent, bio-accumulative and toxic (PBT) substances). Manufacturers or users of such substances can apply for authorisation from the European Chemicals Agency. The agency has to handle and decide on this application within a given period of time. Authorisation is given if the use is sufficiently controlled; this means in particular that existing thresholds are met. If thresholds cannot be defined or if the substances have PBT characteristics, authorisation will only be given if the socio-economic benefit is higher than the risks and if no suitable alternatives exist.

\(^\text{20}\) While the code of conduct for responsible nanosciences and nanotechnologies research (COM 2009) argues for a voluntary adoption by the member states, REACH is an overarching legislation (COM 2008, p 4).

REACH is one possible licensing procedure that could be used if nanoparticles were generally considered as new chemicals, as recommended by the Royal Society (2004, p. 71 ff.). A nanoscale substance would then be newly registered according to REACH or, in the case of SVHCs, would have to be justified on a case-by-case basis. Renn and Roco (2006b, p. 98) also recommend treating nanoparticles as new substances. Shifting the burden of proof, these recommendations suggest a ‘step-by-step procedure’ obvious against the background of a newly established European regulation for chemical substances. However, it should be kept in mind that this is not intended in REACH, where the term ‘nano’ is not mentioned. In addition, the REACH parameter that determines the different registration criteria is the production volume in tonnes per year. The intervals are 1–10 t/a, 10–100 t/a, 100–1000 t/a, >1000 t/a. This differentiation by weight could be a general problem for nanoparticles, because they can total to huge numbers of particles without reaching a noteworthy total weight. So it is possible that a large part of nanoparticle manufacturing will remain below the limit of one tonne, or in the lowest interval regulated by REACH, where the requirements for registration are very simplified. Furthermore, the uncertainty regarding the methods of toxicological assessment of nanoparticles has also to be taken into account. The registration according to REACH refers to the usual material properties established in macroscales. These could turn out to be less relevant in the nanoscale, while some decisive criteria could also be missing in the nanoscale.

Overall, against the background of the Europe-wide agreement and the topicality, REACH can be used as a reference point for the regulation framework of nanoparticles. However, nano-specific aspects like large numbers of particles in combination with low weight and uncertainties concerning the application of procedures established in the macrosector have to be considered as well. We explicitly want to point out that we do not suggest the application of REACH without further discussion on a global level. Nevertheless, REACH – which was comprehensively discussed and negotiated in Europe – constitutes a good basis for possible international regulation activities.

- Choice of appropriate measures

Finally, we will discuss some concrete suggestions on how nanoparticles could be handled in the future. Arguing that a high level of protection is anticipated can hardly justify harsh measures like a ban on the manufacturing of nanoparticles. Nevertheless, a level of protection that is appropriate to the ‘reasonable’ risk level should be obtained. Especially against the background of the high innovation
potential of nanoparticles (e.g. for materials development), another criterion for regulation that favours the continued research on, and development of, nanoparticles are cost-benefit analyses. This idea is foreseen in REACH for the regulation of SVHCs. In such cases, it is requested that the socio-economic benefit of SVHCs has to outweigh their risks, and that information on possible alternative substances, the so-called substitutes, has to be provided as well.

From an environmental point of view, the cost-benefit analyses must also take into account that some applications of nanotechnology and materials development claim to deliver ‘better’ products, particularly regarding their sustainability (Fleischer, 2003; Steinfeldt, 2004). Under the aspect of commensurability, possible alternatives and the considerable effects are further criteria for moderate measures of precautionary regulation of nanoparticles. The request for commensurability of concrete measures is also influenced by considerations on coherence. Some studies refer to other contexts where statements on the level of protection can be found: Nuclear technology and genetic engineering were already mentioned. For genetically modified organisms (GMO) there is a framework of regulations which could be referred to for the formulation of concrete measures. Brune et al. recommend that nanoparticles should be dealt with in the same way (Brune et al., 2006, p. 377 ff.; also Haum et al., 2004, p. 6).

The following suggested measures do not aim at radical regulation but put an emphasis on the pursuit of scientific development as an integral part of the application of the precautionary principle. In addition, they also take up the need expressed in China. Overall, this list of measures is optimised to make efficient monitoring of scientific activities possible. The registration of nanoparticles would be regulated on a case-by-case basis and monitoring would be facilitated by the attempt to categorise nanoparticles according to their effects. This is in accordance with the measures recommended in other studies (Haum et al., 2004; Brune et al., 2004; Royal Society, 2004) but goes further in some respects.

- Nanoparticles have to be classified as new substances.
- Screening methods have to be developed for nanoparticles already in use.
- Life-cycle analyses of products containing nanoparticles allow for predictions about their fate during manufacturing, use and disposal. They should be carried out more often.
- The knowledge base of toxicology has to be broadened with regard to the evaluation of nanoparticles.
- Because of the huge number of toxicological tests that have to be carried out, it should be attempted to classify similar nanoparticles into groups.
• The uncertainties regarding the scientific methods of this classification outlined above shall be outbalanced by the improvement of these methods and development of new ones.
• A dialogue with the public and industry should be initiated to be able to detect discrepancies in risk assessment at an early stage.
• Transparent information should be given on the current state of knowledge.
• The establishment of an institution that collects the findings on nanoparticles and their risks is reasonable.
• Guidelines and – if applicable – standards for the cautious handling of nanoparticles should be developed.

4.6.1. Outlook for China and Europe

If we look at the suggested measures, we can see that several of them have already been initiated although a binding political decision to act according to the precautionary principle has not been taken so far. Research projects in Europe and China are currently investigating the toxic effects of nanoparticles. A transparent and publicly available presentation of the research results is a major aspect of these projects. One of the purposes of the BMBF-funded project ‘NanoCare’ is, for example, to gain new scientific insights into the possible effects of nanoparticles on health. It should also create a structured and interpretable information base, which can be amended by research results of other scientific groups. In addition the information should be comprehensibly presented to the public to satisfy the growing information need in the field of nanotechnology. This is supported by an active dialogue on possible risks which involves different societal actors at an early stage in the discussion (Krug, 2007). The EU-funded project ‘NanoSafe’ [22] faces a similar task: a database with toxicological data should be compiled by its sub-project ‘Health and hazard effects’. Another sub-project of ‘NanoSafe’ deals with the development of evidence and monitoring methods to be applied in the manufacturing of nanoparticles. These ‘joint research projects’ involve partners from industry too. The activities in China, especially within the programme ‘Safety of nanotechnology 973’ have similar aims.

Industry is also acting in the context of nanotechnology. Under the umbrella of Dechema [23], the German chemical industry founded a subject division ‘Nanotechnology’ [24]. The goals of its working party ‘Chemical Nanotechnology’

22 http://www.nanosafe.org
23 Society for Chemical Engineering and Biotechnology.
are, among others, to inform experts, public and policymakers of nanotechnology developments and recommend actions for policy, e.g. needs for sponsorship. The working group ‘Responsible production and use of nanomaterials’ assesses the risks of nanomaterials, especially nanoparticles and nanotubes.

The dialogue with the public is considered to be extremely important, in Europe as well as in China. It is part of the Chinese nanosafety programme, which is partly assimilated to projects in Europe that investigate the toxic characteristics of nanoparticles. Dialogue with the public is one methodological aspect of research projects, for example the determination of criteria for a target group-oriented information platform. Focus groups in the ‘NanoCare’ project revealed that the public hardly differentiates between nanotechnology as such and individual aspects of nanotechnology like the problem of nanoparticles [Fleischer and Quendt, 2007]. In general, there is a broad agreement that the involvement of stakeholders and the public is a necessary condition for successful innovation in nanotechnologies. “Inclusiveness” is the guiding principle under which the code of conduct for responsible nanosciences and nanotechnologies research [COM 2009] frames this kind of participatory approaches. The German “response” to the code of conduct clearly followed this recommendation [NanoKommission 2008, p56, “Prinzip 3”].

There have also been initiatives to inform the public about nanotechnology developments. A ‘Centre of New Technologies’, for instance, has been established at the Deutsches Museum in Munich, and is described as follows:

New technologies change our world. Findings from bio- and nanotechnology raise far-reaching questions, which can yet not be answered by society. The Centre of New Technologies presents controversially discussed questions and latest research results. Try a scanning tunnelling microscope to immerse into the nanoworld. Analyse your DNA. Watch a nanoresearcher at work. Only those who are informed can exert influence (25).

What is remarkable in this short description is the fact that the social dimension of possible controversies on technology are taken into account. It is widely accepted that public debates play a vital part in nanotechnology developments, although it is still not clear in which way.

25 http://www.deutsches-museum.de [Translation MD].
The overall situation can be described as follows: precautionary action has already been applied regarding the development of nanoparticles and their technical applications. According to continuing scientific monitoring of this process, which is a basic element of the precautionary principle, technological assessment is also obliged to update the interdisciplinary level of current knowledge, the subsequent study of (side) effects, their scientific evaluation and the uncertainties of this knowledge. The different databases have to be filled with the results of toxicological and ecotoxicological research and first 'evidence assessments' have to be made. Only then can precise recommendations for action be worked out. To this end, the precautionary principle as a first step in risk management can serve as the basis for action as proposed by the code of conduct for responsible nanosciences and nanotechnologies research (COM 2009). If the member states adopt the principles of the code and if the international dialogue develops in the same direction[26] one will come to a point at which concrete regulatory measures should be developed. Here the lessons learned from the REACH decision making process might become very valuable.

References

Bachmann, Gerd (1998), Innovationsschub aus dem Nanokosmos, Düsseldorf: VDI-TZ.


BMBF (2002), Standortbestimmung: Nanotechnologie in Deutschland.

BMBF (2007), Pressemitteilung 131.

BMU – Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (1992), Konferenz der Vereinten Nationen für Umwelt und Entwicklung in Rio de Janeiro, BMU, Dokumente, Bonn.

http://cordis.europa.eu/nanotechnology/src/intldialogue.htm


COM (2009) Commission recommendation on a code of conduct for responsible nanosciences and nanotechnologies research & Council conclusions on Responsible nanosciences and nanotechnologies research. EUR 23906 EN, Brussels.


ITA (2006), Nanotechnologie-Begleitmaßnahmen: Stand und Implikationen für Österreich, Endbericht 22.6., Studie im Auftrag des BMVIT.


Royal Society (2004), Nanoscience and nanotechnologies: opportunities and uncertainties, Plymouth.


Concluding remarks: towards a common approach to science and technology issues

Miltos Ladikas
This book has a modest aim which is reflected in its size, i.e. to offer the first account of the different approaches that Europe and China have to science and society issues, in so far as these approaches inform science and technology (S & T) policy, and to look for constructive commonalities. This aim was selected for two reasons. Firstly, China is rapidly reaching western levels of investment and output in S & T, and thus is entering similar stages of developmental problems. This situation should bring the two regions into closer collaboration and mutual learning. Secondly Europe and China are often seen as culturally incompatible regions which could not possibly have similar approaches to S & T issues. This is not supported by evidence from S & T policy approaches to similar technological developments. It is with the above in mind that the book sets out to shed some light on how the two regions approach common issues in S & T.

The first inquiry dealt with a very basic question: Do China and Europe understand S & T in the same way? Or, to put it more simply, how different are the concepts guiding choices of right and wrong in S & T in the two regions? The areas of research ethics and bioethics were chosen as the most appropriate to explore cultural and ideological differences. We have seen that, as with most conceptual inquiries, the perspective one chooses to adopt is pivotal to the conclusions that one draws. For instance, ethical differences within Europe on the majority of S & T issues are probably as great as those between Europe and China, but this runs counter to conventional thinking. The case of embryonic stem cell research, for instance, is a reminder that Europe has no single voice when it comes to what is ethical or unethical research. National differences and their respective legislations are as different as one could possibly get regarding an issue relating to new technological developments that are considered to be of a ‘socially sensitive nature’.

That does not mean that there are no real conceptual differences between the regions. We are often reminded that Europe is mainly an individual-oriented society while China (and Asia more generally) is community-oriented. There is naturally truth in this as many examples of different philosophical thinking in the two regions can attest to. Where Chinese sages traditionally praised ritual and obligations to community as guiding principles in life, Europeans chose inner-search and self-actualisation as the most important behavioural guiding principles. Even today there are striking differences between what the two cultures understand by ‘human rights’: does the right of any given individual take precedence over the rights of the community that he/she lives in? Are harmonious relations in society less or more important than the rights of individuals to upset them? These are difficult questions to answer, and the fact that the two regions
have chosen a different ‘weighting’ system to assess their preferred guiding virtues and rights does not mean that the differences are unbridgeable.

As the first chapter showed us, pluralism in ethical thinking is possible. It is evident in current European thinking, and there is no reason why it should not be applied at a global level. As we have been reminded, the issues that a European and a Chinese researcher are faced with are identical and the wish to solve them is also identical. Similarly, the S & T policy issues that European and Chinese governments are faced with are also identical. Cultural differences do not pose difficulties in the search for common solutions; they are the means to identify the missing perspectives and ideas that are necessary when society reaches an apparent impasse. One could argue that understanding how others deal with the same problem is part of the learning curve that will eventually lead to the desired solution. Even if the final decisions are different, they are made in full view and understanding of alternative routes and could therefore be considered more mature and effective. Hence, a pluralistic approach could be the right method to achieve better understanding of each other’s culture, whether or not that leads to the same solutions in the short term.

Policy advisory

Modern S & T is characterised by its proximity to everyday life and the direct effects that it can have on the average citizen. From engineering and building developments to food production and health care, S & T is evident everywhere in modern societies and this has lead to more intense debates on the pros and cons of technological developments. We have seen how the consequences of technical modernity brought into play a new powerful stakeholder in S & T debates: society itself. The technocratic and elitist approach to S & T policy is not accepted anymore by a new generation that requires more control and a more transparent approach to decision-making.

Technology assessment (TA), as a formal advisory service in S & T, has developed new tools and methods to come to terms with the new status quo in S & T debates. We saw how TA has evolved from a technocratic instrument of policy-making advice to a mediator in sensitive social debates that tend to be unpredictable. The power of the media to raise issues at the highest policy level, the will of many non-governmental organisations to challenge conventional wisdom and the increasing power of business lobbies have created an unprecedented
situation in S & T policymaking. TA has thus taken on new roles and functions that deal with the new reality and offer valuable services to policy.

The matrix of TA functions presented in Chapter 2 gives the most comprehensive overview of European TA to date. Despite the many expected differences amongst European nations in their approaches to S & T and their views on the basic principles that guide decision-making, there are still some commonalities in how TA develops along with the social debates on new technological developments. The interactive functions of TA that aim at bringing science and society closer, are ever more popular in Europe and have even assumed the main preoccupation of TA in many countries. The societal aspects of TA, i.e. ‘social mapping’, ‘mediation’ and ‘new decision-making processes’, as they are described on the matrix, represent the new functions of TA in its aim to embed society responsibly into S & T policymaking.

It is prudent to remind ourselves that so far the new reality of science and society being stakeholders in policy debates on an equal footing is neither properly assessed nor stable. There are too many uncontrollable parameters in this ‘social experimentation’ to allow us to draw certain conclusions. Various methodologies in interactive TA are vying for the prize of the best solution to S & T issues but most of them depend more on successful lobbying and current political thinking than proper arguments about their effectiveness in policymaking. As Europe expands and tries to keep its world-leading position in S & T through the establishment of the so-called ‘knowledge society’, more professional effort is needed to create a stable relationship between science and society.

The Chinese perspective

China’s S & T system is characterised by a more centralised structure than that of its European counterparts. The State Council is the ultimate decision-maker and overseer of S & T policies while the Ministry of Science is the main executive branch. As with many European countries, about one third of R & D expenditure derives from the public domain and, as such, the role of the government is still important in deciding the vision and direction of the whole sector.

China has made great steps in recent decades towards an S & T-based economy, a fact that is partially proven by the increasing expenditure and outcomes in the sector. Since the mid-1990s, R & D expenditure has increased exponentially
reaching 1.4% of GDP in 2006 (the EU average being around 1.7% in the same period) and projected to reach 2.5% by 2020. This, in parallel view of the fact that the GDP is projected to quadruple during the same period, shows the immense potential of the country’s S&T. Although there is still some way to go to reach the expenditure level of many developed countries, China is already second only to the USA in terms of absolute numbers in R&D personnel and one of the world leaders in high-intensity technologies such as nanotechnologies, new materials and genetic engineering.

The advisory structures in China’s S&T policy are less well established than their equivalent counterparts in Europe. Whereas State organisations such as the Academy of Sciences, the Academy of Engineering and the Association for Science and Technology function as quasi-informal government advisory bodies, their role in the process of decision-making is still vague and disputed. New organisations that take a TA approach similar to that seen in Europe, such as the Chinese Academy of Science and Technology for Development (Casted), are rapidly establishing themselves as the de facto advisory bodies of the Ministry of Science and hence, of central government in the area of S&T policy.

TA institutes like Casted follow an approach that is mainly of the ‘classic’ (i.e. technocratic) kind, but they are rapidly expanding their methodology towards more interactive approaches that are inclusive of wider stakeholder perspectives. Examples of the new approaches, such as the Wenchuan public survey and the foresight activity on six key technologies, attest to the changing nature of S&T policymaking processes in China. Societal perspectives are becoming more prominent in the construction of advice, both indirectly, through the increasing involvement of social sciences in the decision-making process, and directly, through public surveys that are used as barometers of public perceptions in S&T issues. More importantly, there appears to be a clear political will to bring science and society closer together and avoid the pitfalls of diminishing public trust in science that are evident in Europe.

The case of nanotechnology

A case study where one can observe a technological development that is of equal significance and creates similar issues in the two regions, is that of nanotechnology. Considered to be one of the key technologies of the 21st century, nanotechnology is still lacking an internationally accepted definition, except for
general agreement on its (nano) scale. It is a very pervasive technology with applications that cover a huge spectrum from medical devices and sunscreens to electronic devices, paints, tyres, etc. The total estimated value of global nanotechnology-related revenues could reach one trillion euro in the next five years but the overall optimism is balanced by considerable worries about it.

Nanoparticles produced by nanotechnology are highly evasive due to their size, show different characteristics and behaviour than similar structures of normal size, and cannot be properly assessed by conventional toxicological tests. Their effect on health is naturally an urgent theme but other worrisome themes are their effect on the environment, flora, fauna, biological systems, etc. It is argued that there is hardly an aspect of life on the planet that will not be potentially impacted by developments in nanotechnology. As such, debates on potential risks are increasing in frequency and intensity, a trend that is equally evident in Europe and in China.

Europe has experienced a number of similar risk-debates in the past century on new technologies such as nuclear energy and biotechnology. The turmoil that the uncertainties of these technologies brought in society led to the introduction of the concept of the ‘precautionary principle’, which basically states that if there is uncertainty about serious potential risks in a new technology, policy should err on the side of precaution and remove its application from the public domain. The same principle has been evoked by a number of stakeholders in the nanotechnology debate. Demands for a moratorium on the manufacturing of nanoparticles have also been made, although without success so far. Moreover, organised lay groups (e.g. NGOs and citizen initiatives) are becoming important stakeholders in the debate and, contrary to similar situations in the past, are taking part in industry-led initiatives in the area. In nanotechnology there seems to be a wide realisation of the importance of open dialogue with society.

China has developed a very similar debate on nanotechnology that concentrates not only on risk but also on ethics issues. The issues of nanoparticles’ evasiveness and uncertain effects on health and the environment are also the prime concern, and many actions in expanding scientific knowledge of risk assessment in the field have been initiated. At the same time, discussions on ethical issues associated with nanotechnology developments, such as possible applications in human genetic manipulation and military technology, are discussed with increasing frequency and openness. Calls to apply the precautionary principle as it is understood in Europe are also becoming more prominent and initiatives to open dialogue with the public have been introduced in official programmes.
Overall, the debate on nanotechnology is ongoing in both regions. Solutions to the problem of risk assessment have been suggested (e.g. using the regulatory framework for chemical substances as it is developed in Europe) and new problems have also surfaced (e.g. methodological weakness in toxicology testing procedures). But what is remarkable in this case, is that there is a clear and unambiguous desire to engage in open dialogue with society and take opinions seriously in the management of this technology. This is true for both Europe and China, and perhaps signifies new possibilities for common approaches to common problems in both regions.

Towards a common approach

Overall, it is evident that the two regions need to deal with similar issues, and they appear to be dealing with them with a common understanding that new technological developments require new and more inclusive decision-making processes. The penetration of S & T in everyday life is not of course only a western phenomenon, and similarly the need to develop better risk assessment methodologies and take public worries into consideration, are also common issues. Europe had the fortune, although some might call it misfortune, to have dealt historically with serious turmoil created by the ‘invasion’ of unwanted technological developments in everyday life. This has provided a wealth of experience in how to approach (and how not to approach) technology from a socially sensitive point of view. China’s technological developments are too recent to have created a similar experience but the country is rapidly catching up in both its developmental stage and debate needs in the sector.

It is evident that in cases where technology is equally well developed in the two regions, the problematic accompanying it is similar and the direction of decision-making is also very similar. This comes as a surprise only to those that concentrate their attention on the differences rather than the similarities between Europe and China. And there are indeed many differences, although some could argue that these are not greater than the ones we witness within Europe or even between different Chinese regions. If we decide to focus our work in finding commonalities and devising common approaches, we will find a fertile ground of similarly minded scientists, decision-makers and public alike.

Research collaborations between Europe and China are new and rapidly developing. EU research programmes are open to Chinese researchers and the new
Chinese research programmes are also open to European researchers. It was through such collaborations that this book became a reality and it is also through this route that common approaches will be further discussed and decided upon. The interplay between science, society and policy is a new area of international research collaboration between Europe and China that promises better understanding and closer ties between the two regions.
Annex – Author biographical notes
Michael Decker, PD Dr rer. nat., studied physics (minor subject economics) at the University of Heidelberg, 1992 diploma, 1995 doctorate at the University of Heidelberg, 2006 Habilitation at the faculty of applied sciences of the University of Freiburg with a study on interdisciplinary research for technology assessment. From 1995 to 1997 he worked as scientist at the German Aerospace Center (DLR) in Stuttgart, 1997–2002 member of the scientific staff of the Europäische Akademie GmbH. He was manager of the project ‘Nanomaterialien, Nanodevices, Nanocomputing. Status quo and Perspectives’. Since 2003 he has been a member of the scientific staff and since February 2004 vice-director of the Institute for Technology Assessment and System Analysis (ITAS) at the Forschungszentrum Karlsruhe. He chairs the coordination team of the German-speaking technology assessment network. Main research areas: TA of nanotechnology, pervasive computing and robotics, comparison of TA-methods and interdisciplinary research for policy advice.

Contact details: www.itas.fzk.de

Selected publications:
Leonhard Hennen, Studied sociology and political sciences, doctor in sociology from Technical University Aachen. After five years as a social researcher at the department of ‘Technology and Society’ at the National Research Centre Jülich (projects on ‘Technology and everyday life’ and ‘Risk-communication’), he was (1991–2005) project manager at the Office of Technology Assessment at the German Parliament, which is run by the Institute of Technology Assessment, Research Centre Karlsruhe. He has been responsible for TA projects on genetic testing, pre-implantation diagnostics, and brain sciences as well as for projects on public acceptance of technologies and technology controversies, sustainable development, research policy and others. He participated in several European projects on concepts and methods of TA (Europta, TAMI). Since 2006 he has been coordinator of the European Technology Assessment Group (ETAG). Research interests: sociology of technology, technology policy, concepts and methods of technology assessment, TA in the field of biomedicine.

Contact details:
Institut für Technikfolgenabschätzung und Systemanalyse, FZK
c/o Helmholtz-Gemeinschaft
Ahrstr. 45
D-53175 Bonn
Tel. +49 2283081834
hennen@tab.fzk.de
www.itas.fzk.de/etag
Miltos Ladikas, (BA, MSc, PhD), is senior research fellow at the Centre for Professional Ethics, University of Central Lancashire, UK. He studied psychology (BA) in Athens and Social Psychology (MSc, PhD) at the London School of Economics with a thesis on the analysis of the debate on biotechnology in the UK. From 1994 to 2000, he held various research positions at the London School of Economics and at the Science Museum, London, in the areas of public perceptions of science and technology and the European debates on biotechnology. From 2000 to 2004, he held research positions at the Europaische Akademie, Germany, and Lancaster University, UK, leading international projects on ‘Functional foods’, ‘Technology assessment in Europe: between method and impact’ and ‘Institutionalisation of ethics in science policy in Europe’ involving European parliamentary and independent institutes of S & T policy advice. In his current position he is further leading international projects in the areas of ‘Technology assessment’ and ‘Pharmaceutical innovation and access to medicines’. His research interests are in the areas of S & T public perceptions, technology assessment and ethics in science policy.

Selected publications:
- Bridges between science, society and policy: technology assessment – methods and impact (2004), Heidelberg, Germany: Springer. (with Michael Decker, eds)

Contact details:
Centre for Professional Ethics,
University of Central Lancashire,
Preston PR1 2HE, UK
mladikas@uclan.ac.uk
Zhenxing Li, received a BS degree in agriculture from the Inner Mongolia National University in 2000, an MS degree in agriculture from the Shenyang Agriculture University in 2003 and a PhD degree in agriculture and biology from China Agriculture University, China. He is currently working as assistant researcher in the Dept of Foresight and Evaluation Research, Chinese Academy of S & T for Development. His research interests are technology foresight and evaluation, strategy for basic research and advance technology development, S & T of agriculture and biology.

Selected publications:

**Niall Scott**, is Senior Lecturer in Ethics in the International School for Communities Rights and Inclusions at the University of Central Lancashire. He has studied biology theology and philosophy. He the course leader for the MA in Bioethics and Medical Law at UCLan and also teaches on the undergraduate degree programme providing modules as wide ranging as science fiction and philosophy, Kantian ethics and film and philosophy. His research interests lie in the fields of bioethics, ethics, political philosophy and philosophy and popular culture. He has published material and spoken internationally on bioethics, and on altruism and is the co-author of the book *Altruism*, written together with Jonathan Seglow, published by Open University Press. He is the secretary for the Association of Social and Legal Philosophy (ALSP), a project leader for inter-disciplinary.net and a member of both the Anarchist Studies Network (ASN) and the European Society for Philosophy Medicine and Healthcare (ESPMH).

Contact details:
International School for Communities Rights and Inclusions
University of Central Lancashire
Preston
Lancashire
PR1 2HE
United Kingdom
nwrscott@hotmail.com
**Xinghua Zhu**, is an assistant professor of Chinese Academy of Science and Technology for Development (Casted), Ministry of Science and Technology (MOST) since June 2003. He has a master’s degree in management of science and engineering and a bachelor’s degree in environmental engineering. Since becoming an assistant professor at Casted, he has applied himself to the research on policies of science and technology governance related to technology innovation and project management, and has taken part in over 15 research tasks mostly consigned from the Chinese government in Casted, such as ‘Study of technical standards to trade for some key products’ (2003), ‘Study of government functions of public S & T and the 11th five-year S & T programme system’ (2004), ‘Study of S & T development policies in some key industries’ (2005), ‘Study of the mechanism of innovation platform and case study of industry road mapping’ (2007), ‘Study of organising and management for S & T commonweal projects’ (2008). He is the author of some 40 research articles published in the above fields in Chinese journals.

Selected publications:


Contact details:
Casted, No 8 Yuyuantan Nanlu, Haidian District, Beijing, 100038, PR China
zhuxh@casted.org.cn
How to obtain EU publications

Publications for sale:
• via EU Bookshop (http://bookshop.europa.eu);
• from your bookseller by quoting the title, publisher and/or ISBN number;
• by contacting one of our sales agents directly. You can obtain their contact details on the Internet (http://bookshop.europa.eu) or by sending a fax to +352 2929-42758.

Free publications:
• via EU Bookshop (http://bookshop.europa.eu);
• at the European Commission’s representations or delegations. You can obtain their contact details on the Internet (http://ec.europa.eu) or by sending a fax to +352 2929-42758.
This book is the result of a series of discussions initiated by an FP6 project carried out during the year 2007 and which focused on issues of Science and Technology (S & T) governance and ethics in Europe and Asia. The discussions were highly successful, not only in increasing mutual understanding between the two regions, but also in producing a series of collaborative initiatives between Europe and China on bringing science and society closer together.

The main purpose of this book is to provide an actual analytical description of the different facets of Science in Society (SiS) in Europe and China. It also gives an overview of the lessons learned and provides some thoughts on the next steps that are needed to bring the S & T policy of the two regions closer together under a common understanding.