MEMORANDUM OF UNDERSTANDING

Subject: Memorandum of Understanding for the implementation of a European Concerted Research Action designated as COST Action IS1001: Bio-objects and their boundaries: governing matters at the intersection of society, politics, and science

Delegations will find attached the Memorandum of Understanding for COST Action IS1001 as approved by the COST Committee of Senior Officials (CSO) at its 178th meeting on 25 May 2010.
MEMORANDUM OF UNDERSTANDING

For the implementation of a European Concerted Research Action designated as

COST Action IS1001

BIO-OBJECTS AND THEIR BOUNDARIES: GOVERNING MATTERS AT THE INTERSECTION OF SOCIETY, POLITICS, AND SCIENCE

The Parties to this Memorandum of Understanding, declaring their common intention to participate in the concerted Action referred to above and described in the technical Annex to the Memorandum, have reached the following understanding:

1. The Action will be carried out in accordance with the provisions of document COST 4159/10 “Rules and Procedures for Implementing COST Actions”, or in any new document amending or replacing it, the contents of which the Parties are fully aware of.

2. The aim of the Action is to improve the understanding of the process of new scientific and technological development, in particular the making, trading and socio-cultural use of new bio-objects emerging at present in Europe, in order to strengthen Europe’s capacity to both exploit and manage the intended and unintended effects of these processes.

3. The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 40 million in 2010 prices.

4. The Memorandum of Understanding will take effect on being accepted by at least five Parties.

5. The Memorandum of Understanding will remain in force for a period of 4 years, calculated from the date of the first meeting of the Management Committee, unless the duration of the Action is modified according to the provisions of Chapter V of the document referred to in Point 1 above.
A. ABSTRACT AND KEYWORDS

Europe seeks to become the most dynamic knowledge-based economy of the globe, and the production and circulation of “bio-objects”, such as stem cells, chimera, tissue samples or genetically modified organisms, play a key part in this endeavour. This Action develops novel interdisciplinary tools based on a range of evidence that will improve our understanding of “bio-objects”, their production and governance. The core questions answered through this COST Action are: how are the boundaries between human and animal, organic and non-organic, living and the non-living opened up? how do bio-objects change social relations? how does the public-private interface shape the making of bio-objects? and finally, how does the governance of bio-objects perform at different levels, from the level of the European Union and its Member States to the sub-political level, and finally in clinics and laboratories? The Action will bring together a group of young scholars across a range of disciplines in collaboration with more experienced researchers, including those from the bioscience community. It will develop models of the bio-objectification process, the policy challenges and political and social resources needed to address this, and how both will play a key role in delivering the knowledge-based economy sought in the Lisbon Agenda. Keywords: bio-objects, bio-objectification process, governance, policy models

B. BACKGROUND

B.1 General background

Europe seeks to become the most dynamic knowledge-based economy of the globe, an objective enshrined in the “Lisbon Agenda”. The production and circulation of “bio-objects”, such as stem cells, chimera, tissue samples or genetically modified organisms, play a key part in this endeavour. “Bio-objects” is a concept proposed by the Action to cover a number of biological entities, which are distinct and diverse in biological terms, but which nonetheless share a number of challenges in regard to their production, circulation and embedding within society. The concept of bio-objects allows these challenges to be studied under a common conceptual and methodological framework.
This Action will develop and disseminate interdisciplinary social science tools that: a) link and compare research findings across new biological entities under the common concept of bio-objects; b) improve our understanding of bio-objects, their trajectories from their conceptual and material development to their application and circulation in society, as well the challenges associated with these movements; c) improve policy practices and facilitate their governance.

Biotechnologies and new biological artefacts are currently disrupting the conventional boundaries and identities of biological forms—whether human, animal, plant or synthetic. New life-forms, such as pluripotent stem cells outside of bodies, synthetic biology or genetically modified organisms, create new clinical, commercial and regulatory possibilities and demands. This Action conceptualises these different life forms as material articulations of bio-objects. These are characterised by ever-greater fluidity and mobility across different domains. This means that a bio-object associated with biomedical research may find its way into the food system or the environment, become part of a repository (as in biobanks or cord blood banks), and have multiple or even contrasting cultural meanings as it circulates between different sectors of society. At the same time, new regulatory boundaries are developed for what human and non-human material can and cannot be legitimately traded as bio-objects (for example, oocytes and embryos).

The Action develops a novel and timely examination of the making, trading, and governance of bio-objects associated with a number of domains – clinical, public health, regulatory and commercial. It will seek to answer the following questions:

- How are the boundaries between human and animal, organic and non-organic, living and the non-living opened up?
- How do bio-objects change social relations?
- How, within this, does the public-private interface shape and steer the making of bio-objects?
- How does the governance of bio-objects perform at different levels, from the level of international or transnational regulatory bodies, particularly within the EU, to the level of nation states and the sub-political level in clinics and laboratories?
And further:

- What analytical tools can be developed to track the “life cycle” of a bio-object, from its conceptual and material creation to its later uses and re-creations in society?
- How can these analytical tools be translated into tools that are amenable to inform policy practices?
- How can these tools inform the evaluation of medium or long-term risks (related to safety for example) and identify appropriate forms of governance?
- How can such tools be adapted to differing contexts and levels across Europe and European states, and the EU and its Member States?

This COST Action aims at consolidating the already existing scientific research results on bio-objects that have been generated over recent years to further extend and develop theoretical and methodological tools for examining the production and circulation of various bio-objects thanks to a more transnational and interdisciplinary collaborative effort.

This COST Action would help to:

- Build on existing linkages and research among participants;
- Integrate the evidence base from this work allowing for an analytical approach specifically adapted to the European situation;
- Support a more interdisciplinary approach to the analysis with the addition of bioscientists to the network;
- Offer researchers in the early stage of their career a better opportunity to develop their academic networks with more established researchers.

Moreover, this Action will help to inform policy practices and to improve the governance of bio-objects in Europe. Building on existing research, the Action seeks to enhance its value. It will link this research under the common analytical concept of bio-objects, to compare these findings, and to enable a better understanding of bio-objects and their associated challenges as these circulate from laboratories to society and across different levels of governance.
B.2 Current state of knowledge

The Action brings together a number of theoretical and methodological approaches that have been used within various disciplinary fields to study the production and circulation of both human and non-human bio-objects. Such an undertaking is ambitious since the various strands of enquiry have their own historical trajectories. The Action, however, aims at bringing these trajectories together to examine them as a whole within a broader geographical context that extends across and beyond Europe.

Recent EU-funded work on the biosciences has focused on the risk and uncertainties (PAGANINI; RISK BRIDGE) posed by new developments, on the bioethical (BIONET), legal (Stem Cell Patents) or specifically institutional (GeneBanC) dynamics they engender, rather than on developing a theorisation of the new social relations and challenges posed by bio-objectification itself. Outside of the biosciences, earlier Framework Programme 6 (FP6) work (e.g. STAGE) offers very useful accounts of different types of governance regimes that will inform the Action’s work, though these remain primarily at the formal level of the state. A current Framework Programme 7 (FP7) study (REMEDiE) is providing important results on the global political and economic processes associated with regenerative medicine. While these studies are of real value in identifying some of the key factors shaping the place of bioscience innovation or governance regimes in Europe, they do not track the movement of bio-objects in space across different social contexts and in time from their conceptual and material creation to their deployment and circulation. These spatial and temporal iterations and reconfigurations can create major societal concerns, whether this be in terms of failings in the existing regulatory institutions to manage such developments or imposing new burdens on people (as citizens, family members, consumers) who often struggle to know how to respond. It is important therefore to know how new bio-objects engender new or mobilize existing social relations and expectations and to analyze the scale and extent of cultural, institutional and regulatory challenges that they pose across Europe. The Action explores these challenges as they arise in different substantive domains, Member States and different levels of European governance so providing a rich and systematic interrogation of their import and long-term effects.
B.3 Reasons for the Action

It is becoming increasingly recognised that one of the strategic research and policy challenges facing government is the mobilisation and translation of knowledge-based capacity into outcomes that provide real benefit for society and the economy. At the same time, innovation produces intended effects as its outcome – such as biobanks or tissue-engineered medical devices – and opens up new and often unforeseen questions about the proper management and harnessing of these innovation products and about what is possible and desirable. Focusing on the bio-sciences as a key area of innovation in contemporary Europe, this Action provides a detailed examination of their forms of innovation and their products, i.e. bio-objects. It will track the significance and impact of bio-objects and explore whether and how their opportunities – for example in commercial arenas such as regenerative medicine, insurance, or therapeutic products – can only be realised through anticipating the new demands they will make. One of the distinctive benefits of the Action is to provide new methodological techniques based on an understanding of the process of bio-objectification that can model the current and likely future policy and societal challenges across Europe in a different way. The Action addresses the new questions around these innovations by exploring the spatial and temporal iterations. In this way, the diverse range of bio-objects under consideration can be modelled and so the data on which the Action will draw more effectively integrated.

The Action is then focused on immediate as well as long term needs: for example, there is an immediate need to understand how to oversee and regulate international exchange of tissue samples across European stem cell banks as is currently the case between Spain and the UK; in the long term there is a need to understand how the resources such public banks hold will be open to private exploitation through commercialisation. Similar more immediate and longer-term needs characterise developments in areas such as the national mobilisation of genetic resources or the arrival of new diagnostic techniques that are redefining the traditional boundaries of a specific form of bio-object, disease itself.
In light of this, there will therefore be a number of concrete outcomes from the Action, including:

- The integration of existing data on various bio-objects that will enable the development of models of bio-objectification that identify more, or less, problematic policy challenges;
- The provision of policy guidance in respect to how to meet the concerns that the rupture of conventional ‘natural’ boundaries poses to society, culture and the European citizen;
- The development of dialogue between social and natural sciences and the opportunity to explore how this might be made more effective through building debate over the meaning of data, problem-definition and its resolution.

This last outcome will help support the transformation of the EU to a leading knowledge-based economy by enhancing the Community’s capacity to govern the interplay between scientific development and societal needs in a competent and publicly legitimate manner.

**B.4 Complementarity with other research programmes**

There are no complementary European research projects in this area (apart from those referred above in B.2, which do not trace the trajectories of bio-objects along their temporal development and across geographical and political space). It is, however, a long-term goal of the Action to form the basis of one or more Framework Programme applications in the future.

**C. OBJECTIVES AND BENEFITS**

**C.1 Main/primary objectives**

The main objective of this Action is to improve the understanding of the process of new scientific and technological development, in particular the making, trading and socio-cultural use of new bio-objects emerging at present in Europe, in order to strengthen Europe’s capacity to both exploit and manage the intended and unintended effects of these processes. The Action will draw upon and extend existing knowledge by integrating different attempts to analyse bio-objects into an interdisciplinary framework. The objective of the Action is to foster the elaboration and dissemination of interdisciplinary analytical tools to better understand the process of the movement of bio-objects in space across different socio-cultural settings and political domains.
C.2 Secondary objectives

A secondary objective of this Action is capacity building, aiming at the building of a strong network that unites young researchers with different disciplinary backgrounds in different European countries. The main target of the Action are young scholars at an early stage of their career, but also more established scholars will be drawn upon to deepen and broaden the expertise of the network.

In quantitative terms, it is expected that at least 30% of the working papers that will be produced will be co-authored across countries, while each year, apart from the series of workshops, about 20 Short-Term Scientific Missions are envisaged across the network. At the Action’s workshops, young researchers should constitute 60% or more of participants while at least 5% of participants should be policy-makers. The Action will organise specific sessions relating to the three axes described below in section D (relating to changing boundaries of bio-objects, their governance and their future impact).

C.3 How will the objectives be achieved?

In order to achieve its objectives, this Action will host a series of virtual and actual meetings, workshops and conferences that bring scholars and policy-makers exploring different examples of bio-objects in different contexts together. Through bringing together work of Action members and of previous EU-funded work, this Action will allow the systematic comparison of challenges across three dimensions - substantive domain, country, and different levels of European governance - and, based on this comparison, to elaborate empirically grounded, interdisciplinary tools that allow more systematic examinations of bio-objects in the future.

The Action will disseminate the results to key agencies within EU Member States and the European Commission, and through workshops involving public, scientific and regulatory stakeholders. In order to ensure the policy relevance and take-up of the results of the Action, one ongoing (though not sole) theme in each workshop will be how the current oversight and promotion of bioscience innovation involves the allocation of distinct political resources to different political channels within the EU and Member States policy cycles and what informational demands this requires.
The Action will also seek to track how issues and interests associated with them evolve over time, affecting different levels of actors and their networks. The Action will also try to answer the following question: what policy learning between the European and Member States level goes on and how can an understanding of the intended, unintended and unforeseen processes associated with past, present and future bio-objectification enhance such learning? Another specific issue will be to research into the extent to which the current regulatory controls are capable of ensuring a safe and profitable development of the European bioscience industry - this is especially true, for example, in regard to the deployment of stem cell technologies in both clinical and non-clinical domains.

C.4 Benefits of the Action

The principal benefits of the Action are scientific, policy-relevant and capacity-building. The Action will build new social scientific models of those factors that enable or constrain the making, circulation, and governance of bio-objects, and integrate research that has so far not been connected.

From a policy perspective the work will benefit Member States and European Commission agencies associated with foresight, ethical, public engagement and the regulation of the biosciences by providing tools that can be used to determine the likely opportunities, risks and limits of emergent biologies (associated with regenerative medicine, transgenics, cloning, system biology, synthetic biology and epigenetics). COST support will also provide a European dimension and the opportunity for comparative work and build capacity among a group of young researchers in the early stage of their careers.

C.5 Target groups/end users

In light of the above-mentioned benefits of this Action, the likely end-users include: policy makers and regulators; members of the network and other academics concerned with the creation and diffusion of novel bio-objects; and students of the home universities of the network members.
In addition, the Action will disseminate its results to those consumer and citizen-based organisations with a substantive interest in the impact of the new biosciences, such as patient organisations, insurance companies and smaller firms seeking to develop new products (effectively new bio-objects) in an uncertain regulatory environment.

D. SCIENTIFIC PROGRAMME

D.1 Scientific focus

The Action is organised around three main scientific axes: the first axis will examine the changing boundaries of human, nonhuman and society with the emergence of new bio-objects; the second axis will explore the governance of bio-objects across different levels of governance ranging from the EU to the national and the sub-political level; the third axis will analyze new social and economic relations emerging around these changes.

1) Boundary changes between human/non-human and living/non-living

The urgency to study the shifting boundaries of ‘the living’ stems from the intertwined developments put forward, on one hand, by the new technologies capable of genetically transgressing what once were thought of as “natural” boundaries between categories of living, such as in the case of transpecies mice or hybrid embryos. Such categories put into question by the new technologies were most often defined by biological taxa, e.g. as natural species. On the other hand, simultaneous theoretical and technological advancements in wide range of biosciences question boundaries within categories of living, such as the life/death border or what counts as genetic and biological and non-genetic and social.

Furthermore, instead of seeing the role of biology as solving the “mysteries of life” (including the current biomedical fields) and the functioning of already existing entities, its societal mandate and praxis turn towards crafting new entities, thus producing the biological and hitherto unknown potentials within it. Such new knowledge and related practices that transgress old boundaries of living can be witnessed e.g. by the rise of synthetic biology and bioinformatics as well as within “older” practices of biosciences including for example biobanking, xenotransplantation, or in vitro fertilisation.
The first axis of this Action explores the question of how the biosciences and their products, i.e. bio-objects, challenge, change, or reify boundaries across and within categories of the living in several key sites around Europe. It draws on the network’s current research notably in relation to the existence of transgenic beings and the practices that constitute them, re-naturalised connections between nations and their genetic natures, and the creation of artificial bodies. It traces how and where new boundaries between life and death, human and nonhuman, natural and artificial are drawn in novel bioscientific knowledge-practices, and explores how these “new” boundaries relate to “familiar” ones. It investigates how, as a result, new categories of life and living – bio-objects – are imagined, theorised and performed within European bio-sciences.

2) The governance of bio-objects

The second axis of this Action explores the governance of bio-objects. In a very literal way, the development of both the technologies of life and living as well as the underlying theory of new biosciences (albeit scattered under many different subfields) have great impact on how “life” is defined, and how it is integrated into society. Therefore, the second axis draws on research that concentrates on the governance of new bio-objects and the socio-cultural and political regulations involved in the boundary shifts that they bring about. The second axis of the Action will bring together current research that covers different modes of governance of bio-objects, such as the regulation of cloned animal products, different forms of public engagements with genetically modified organisms, governance regimes around tissue banks and the paradoxes involved in the governance of life-not-yet-born through new testing technologies (such as pre-implantation genetic diagnosis).

Currently, governing bodies as we know them, such as parliaments or established advisory boards, and newly established bodies, such as bio-ethics-committees, as well as regulatory and legal regimes in the Member States and on the EU level, are seriously challenged by the introduction of novel bio-objects. Indeed, these cut across several institutional and legal regimes, circulating across national borders or sitting uneasily between established boundaries of bureaucracies. Paradigmatic examples of the political problems that bio-objects bring to Member States and EU level decision-making are GMOs or human embryonic stem cells. The second axis links data and research to
compare the governance challenges that bio-objects pose across different levels of governance, ranging from the EU system of multilevel governance, to governance regimes located in Member States, to the civic level. In particular, it compares existing practices of governance across these levels, analyses patterns of hurdles and challenges in the current frameworks, and aims at developing an understanding of possible mechanisms and means (institutional, legal, practical) for their future governance.

3) The emergence of new kinds of social and economic relations prompted by processes of “bio-objectification”

The third axis examines new relations engendered and constituted by bio-objects, and the relations and “forces” that—in turn—help to constitute bio-objects, ensuring their circulation through society and the acceptance of this movement. These new relations might be either social, economic or political, or heterogeneous relations combining all these at once. A central tenet of this axis is the assumption that the making of bio-objects and their movement across different settings of society are engendered or facilitated by the emergence of new relations and forces, which demand further investigation. At the same time, however, bio-objects also engender new social, economic or political relations.

In light of these assumptions, this axis includes critical examination of the "newness" of these relations in respect to risk, looking specifically into transforming insurance practices in the molecular age, asking how the circulation of bio-objects such as “risk genes” change existing insurance practices and the social relations in which these practices are embedded. It also explores how collective cultures are changed by new bio-objects within highly individualised societies focusing specifically on the application and uptake of new technologies, such as direct-to-consumer genetic testing. New bio-objects challenge hitherto valid categories for judging their usefulness for application for individuals, regional policy, nations and transnational policy. The emergence of bio-objects goes hand in hand with a digitalisation and globalisation of biomaterial that adds urgency to decisions at the regional, national and international level. International competition is rising with emerging transnational or even global markets and privately funded large-scale research and
transnational science with global development and trading zones gaining more influence in European biosciences. Such transformations shift boundaries between bioscientific and medical disciplines on the one hand and between research and production on the other. An exploration of the changing relations, that engender bio-objects and that are engendered by bio-objects, includes a critical examination of these different transformations and forces shaping bioscience development at the individual, industrial and political levels. Apart from cultural and moral pressures, such forces reflect economic needs and competition, requiring a diverse range of political resources at national and EU level to create appropriate regulatory policies that will shape the future of bio-objects. The axis will investigate how European regulations have performed here through, for example, flexible research and regulatory strategies and pursuing compromises between different national positions and future implications of these or alternative policies.

However, new bio-objects are not reducible to theoretical or practical processes witnessed in the large field of biosciences, nor are they a mere issue of governance. Instead, bio-objects are generative in their effects in that they make novel *individual* choices about the future possible over e.g. genetic screening and designing, or make possible and perhaps necessary the creation of more collective futures as enshrined in the promise of stem cell/tissue banking. In other words, bio-objects are “agential” in wider socio-cultural settings, as they enable and create novel expression of individualisation, population and kinship (e.g. ‘biological citizenship’) and act as their conditions of possibility. These new relations of choice regarding the interaction between the individual and society are also informed by political and economic calculations. The intertwining of the changing meaning of autonomy in decision making of the individual “biological citizen” with the economy of bio-objects is demonstrated by the huge efforts invested by the pharmaceutical industry into the development of “personalised” or “stratified” drugs through genetic tailoring and targeting or political innovation policies aiming at creating national economic growth through bio-science businesses. Highly regulated techniques in Europe such as genetic testing as well as regenerative medicine are not only disputed and controversial; through their commercialisation, they also create hopes in citizens, thereby fostering pressures from citizens on European policies and national
governing bodies. Other stakeholders involved in the shaping of biological citizenship are insurance companies, employers and unions regarding future decision making around ‘genetic insurance’ as a strengthening business sector. Exploring new relations around bio-objects, this third axis of the Action will also investigate the economic implications of new bio-objects, such as the normalisation of genetic practices through commercialisation, and their impact on potential redistributions of responsibilities.

**D.2 Scientific work plan methods and means**

The three axes will be integrated through developing a model of bio-objectification across domain, country and governance dimensions, thereby producing both a prognostic and critical forward look which will inform policy analysis.

The scientific work will be structured in three Working Groups, each of which is responsible for one of these axes (see E.2):

- Boundary changes between human/non human and living/non-living;
- Multi-level governance of bio-objects;
- The emergence of new kinds of social and economic relations prompted by processes of ‘bio-objectification’.

The work plan of this Action contains several steps with a feedback process in which the three Working Groups individually try to answer their problems and bring them back to the plenum of groups. At the start of this Action, all three Working Groups will collect existing data and research findings generated by their members. This means that the first Working Group on Boundary changes between human/non-human and living/non-living will define boundaries across and within categories of the living at stake by bio-objects in several key sites around Europe and describe how they change what can count as genetic and biological and non-genetic and social.
The second Working Group will investigate the governance of new bio-objects and the socio-cultural and political regulations involved in the boundary shifts that they bring about. It will compare existing practices of governance across different political levels, will analyse patterns of hurdles and challenges in the current frameworks, and will develop an understanding of possible mechanisms and means (institutional, legal, practical) for their future governance.

The third Working Group will focus on interrelations, thus it will investigate new forms of citizenship, and of relations between citizens prompted by processes of “bio-objectification” and their economic implications.

Subsequently, these data and findings will be contrasted and compared with the findings of the other groups and across countries, across settings and contexts. This comparison will identify commonalities and differences and explore key variables that cut across different cases. These variables will be built into the emergent models. These will be tested in the various Workshops with the help of specific cases.

The three axes in the study of bio-objects will be interrogated through network workshops of those from political science, sociology, women’s studies, social psychology, anthropology of science, philosophy, as well as participants from within the biosciences. Apart from the interdisciplinary Working Group meetings, the Action will arrange targeted expert meetings with politicians, scientists, and stakeholders, focussed on the different axes, to ensure ongoing engagement with their concerns.

Apart from online meetings in internet-fora, the Management Committee will meet twice per year to develop integrative papers and reports, prepared for different audiences, ranging from social science peers, members of the public, patient groups, to stakeholder and policy makers. Relevant lecturers and guests will be invited to these meetings, the aim being to bring in knowledge and thus strategically strengthen the competence of the Network.
E. ORGANISATION

E.1 Coordination and organisation

This Action is designed to undertake a series of integrative and policy- and dissemination-related activities. The Action will be organised through a management structure that is responsible for the coordination and organisation (See E.1) and three specific Working Groups (see E.2).

The coordination and organization of the Action will be overseen by a Management Committee, directed by a Chair, a Vice-Chair and a Secretary that together form the Steering Committee. In addition, the Action will be managed by the Chair who receives administrative support from the Action Office. An Editorial Board will oversee the publications that will result from the Action and an International Advisory Group will advice the Action. In collaboration with the Working Groups (E. 2), this coordination structure will ensure that the milestones of the Action will be reached.

The Action will be overseen by a Management Committee (MC). The MC will consist of up to 2 nominated representatives from each country which accepted the MoU, according to COST guidelines.

The Chair, the Vice-Chair, and the Secretary of the MC will be elected at the first meeting of the Action and together, they will form the Steering Committee (SC).

The MC will be responsible for the overall coordination of the Action as described in Section C and D as well as the liaison with other relevant programs and organisations. It will meet twice a year in different host countries. Additional experts can be invited to these meetings. Specific tasks of the MC are to:

- Appoint the Working Groups (WG);
- Solicit and approve a work plan from each WG, including clear milestones and deliverables;
- Review and approve the reports of the WGs, decide on changes in work shares as well as acceptance of new members or withdrawals or exclusion of members;
- Review and approve the accounts for the past (financial) years, approve the Budget and Implementation Plan for the next (financial) year;
- Coordinate the interaction between the WGs;
- Monitor the progress of the Action according to the milestones defined in Section F.

The Chair will report to and advise the Management Committee both at and between formal meetings. The Chair will also ensure the provision of all data and reports to COST including the deliverables specified in the MoU.

The Action Office will remain in regular contact with all Action members, in particular the Steering Committee, and facilitate the preparation of the various workshops and related events. The Office will also house the dedicated Bio-objects website, which will carry all updated reports, as well as a series of working papers and policy briefs that will form the basis for more formal publications during the four years of the Action.

There will also be an Editorial Board established to oversee the production of publications from the Action, most importantly a book that will summarize the main results of the Action.

An International Advisory Group (IAG) will be an important resource to provide advice to the Action, help in extending academic, policy, and public/community links for the dissemination of results, and counsel with respect to the governance of the Action. The Group will be drawn from the preliminary list of experts/participants and will be composed to reflect a range of social science, humanities and biosciences and bioethical experts, including policy-makers from Europe with an interest in new bio-objects and their production and diffusion. The IAG will meet once per year immediately prior to the MC meeting.

*Milestones of the Action*
As COST provides funding for the coordination of research that is carried out in and financed by the participating countries, the milestones of the Action focus on the integration, coordination and dissemination of research.
The Action will organize workshops to which academics outside the Action as well as policy-makers, patient organizations, etc. will be invited. These will run approximately every 9 months to ensure ongoing engagement. This will facilitate a broad exchange of ideas and the dissemination of results. The workshops will feature work from the three Working Groups (See E. 2). The workshops are sequenced in such a way that the core information about the European contexts (research, clinical, economic) will be secured along with comparison of data on the pattern of bio-objectification. This will allow the Action members to maintain an overall perspective. The first workshop will be used specifically to make the Action known to researchers not yet participating.

The Action will develop a website which will carry all publications produced during the four years of the Action. This is housed and updated by the Action Office to provide information about ongoing research, seminars, publications and other activities.

Every year the Action will lead to a number of publications. It will develop an annual report and a policy brief which will also be published on the website. In addition, joint working papers as well as international peer-reviewed articles will be developed. One edited book will also be written.

A further important pillar of the Action is the short-term exchange of researchers. This will be especially beneficial for young researchers at an early stage of their career to get better connected in the scientific community and to provide a framework for interaction with senior researchers.

These milestones are also part of the more detailed Timetable (Section F).

**E.2 Working Groups**

The Action is structured in three Working Groups, each of which is responsible for a coherent research area, according to the three scientific axes noted above (D.1. and D.2.): boundary change between human/non-human and living/non-living (WG1); multi-level governance of bio-objects (WG2); the emergence of new kinds of social and economic relations prompted by processes of ‘bio-objectification’ (WG3).
The Working Groups are the think-tanks of the Action and provide the input for workshops and publications. All scientists participating in the Action will be invited to join one or several WG, depending on their research interests. Each Working Group has a designated lead and Working Group members will be required to contribute to the analytical integration of the Action. This integration will be facilitated by cross-cutting themes that are found within the three axes, such as globalisation, innovation, bio-economy, and governance.

This analytical approach will encourage organisational integration across the Working Groups and ensures clear expectations on network members from the start. In addition, their input into the modelling, policy and dissemination planning and delivery will ensure joint working throughout the four years beyond their immediate Working Group responsibilities.

E.3 Liaison and interaction with other research programmes

Liaison with other programmes and organisations will be managed by the Management Committee. These include:

1) Interaction with other European programmes: some of the potential members of this Action have already been heavily involved in FP6 and FP7. However, these programmes are focused on the risk and uncertainties posed by new developments, on the bioethical, legal or specifically institutional dynamics rather than on developing a theorisation of the new social relations and challenges posed by bio-objectification itself. Representatives of these programmes will be invited to participate in the WGs as well as in the yearly workshop in order to promote integration.

2) In order to improve contact with researchers in other international research programmes, it will be valuable to organise joint events with organizations such as the European Association for the Study of Science and Technology (EASST) and with international graduate schools such as The Netherlands Graduate School of Science, Technology and Modern Culture (WTMC). These will take the form of a two-day training event for postgraduates drawn from institutions involved in the Action.
A major task coordinated by the MC will be the liaison, recruitment and selection of additional members of this Action.

**E.4 Gender balance and involvement of early-stage researchers**

This COST Action will respect an appropriate gender balance in all its activities and the Management Committee will place this as a standard item on all its MC agendas. The Action will also be committed to considerably involve early-stage researchers. This item will also be placed as a standard item on all MC agendas.

The Action will encourage a strong participation of female and early-stage researchers, by promotion and publicity of the Action’s aims among researchers during all phases of their training. Special attention will be focused on these groups with regard to invited speakers at workshops organized by this Action. In addition, both the MC and WGs will have a gender balance and involve early-stage researchers. This allows early-stage researchers to develop not only their scientific, but also management and networking skills. Moreover, the short-term scientific exchanges will allow young researchers to develop lasting contacts by providing them with the financial means to visit other institutions. Finally, the planned training workshop will improve the knowledge of research methods and provides an additional opportunity for networking for young researchers.

**F. TIMETABLE**

The Action is scheduled over a time period of 4 years and is summarised below.
<table>
<thead>
<tr>
<th>YEAR</th>
<th>Milestone to be achieved</th>
<th>Measured in terms of</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Setting up and updating website</td>
<td>Tracked number of website requests grows by 50% on average over first year</td>
</tr>
<tr>
<td></td>
<td>Working Groups established</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plan of action for 4 years by each Working Group</td>
<td>(Internal) plan for Working Groups</td>
</tr>
<tr>
<td></td>
<td>Policy Brief introducing the Action</td>
<td>Policy Brief distributed to key stakeholders</td>
</tr>
<tr>
<td></td>
<td>Meeting Management Committee and Working Groups for installation of network, to further develop plans to meet milestones, to establish links with complementary FP7 projects and consortia</td>
<td>Meeting MC</td>
</tr>
<tr>
<td></td>
<td>First COST Workshop with new members open to external researchers; presentation of projects, preparation of co-authored articles, preparation of joint panels for the EASST-conference 2010; decision on speakers (experts in fields which the group does not entail) to be invited at the second bio-objects-workshop in 2011</td>
<td>Workshop Report and confirmation of participation at Second Workshop</td>
</tr>
<tr>
<td></td>
<td>Plan of action for 4 years by each Working Group</td>
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<td>Workshop Report and confirmation of participation at Second Workshop</td>
</tr>
<tr>
<td></td>
<td>Annual Report prepared</td>
<td></td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>YEAR</th>
<th>Milestone to be achieved</th>
<th>Measured in terms of</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Maintaining website</td>
<td>Updated website carrying new data and open access papers</td>
</tr>
<tr>
<td></td>
<td>Policy Brief with interim results</td>
<td>Policy Brief distributed to key stakeholders</td>
</tr>
<tr>
<td></td>
<td>Management Committee and Second COST Workshop: development of model of bio-objectification and testing its utility with regulatory practitioners</td>
<td>Regulatory practitioners inform final shape of model: co-production of the knowledge-base</td>
</tr>
<tr>
<td></td>
<td>Third COST workshop on bio-objectification model and its value in the lay public domain followed by two-day training event for postgraduates drawn from consortia institutions</td>
<td>Workshop attracts up to 25 doctoral students for training</td>
</tr>
<tr>
<td></td>
<td>Annual Report prepared</td>
<td>Annual Report disseminated and coverage secured in national and international social and bioscience communities</td>
</tr>
<tr>
<td>YEAR</td>
<td>Milestone to be achieved</td>
<td>Measured in terms of</td>
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<tr>
<td>------</td>
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</tr>
<tr>
<td>3</td>
<td>Maintaining website</td>
<td>Updated website</td>
</tr>
<tr>
<td></td>
<td>Policy Brief with interim results</td>
<td>Policy Brief taken up by stakeholders especially in regulatory community</td>
</tr>
<tr>
<td></td>
<td>Fourth COST workshop with bioscience, biocommerce and policy makers</td>
<td>Workshop results inform policy-making</td>
</tr>
<tr>
<td></td>
<td>Management Committee meeting to prepare final report</td>
<td>MC meeting report</td>
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<tr>
<td></td>
<td>Fifth COST Workshop and preparation of publication of special journal issue on bio-objects</td>
<td>Journal publication secured</td>
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<tr>
<td></td>
<td>Annual Report prepared</td>
<td>Annual report focused on third axis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Milestone to be achieved</th>
<th>Measured in terms of</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Maintaining website</td>
<td>Updated website</td>
</tr>
<tr>
<td></td>
<td>Policy Brief with final results of project</td>
<td>Policy Brief</td>
</tr>
<tr>
<td></td>
<td>Edited book published with major international publishing house</td>
<td>Edited book sales and publicity</td>
</tr>
<tr>
<td></td>
<td>Short-term scientific mission (3 months) of academic leads of 3 (Working Groups) dimensions to write scientific report.</td>
<td>Scientific report adopted by lead players in social and bioscience community</td>
</tr>
<tr>
<td></td>
<td>Final international bio-objects conference and dissemination via web, a policy review to the Commission and regulatory agencies in MS.</td>
<td>Conference</td>
</tr>
<tr>
<td></td>
<td>Final Annual Report prepared</td>
<td>Annual Report</td>
</tr>
</tbody>
</table>

**Year 1:**

- First Management Committee meeting; confirmation of plans to meet milestones; establishing a dedicated COST website for the Action with both publicly open and restricted areas; establish links with complementary FP7 projects and consortia to ensure value-added work and new membership.
- First COST Workshop with new members; presentation of projects; preparation of co-authored articles; preparation of joint panels for joint conferences; decision on speakers (experts in fields which the group does not entail) to be invited at the second bio-objects-workshop in 2011
Year 2:

- Management Committee and Second COST Workshop: development of model of bio-objectification and testing its utility with regulatory practitioners.
- Third COST workshop on bio-objectification model and its value in the lay public domain followed by two-day training event for postgraduates drawn from consortia institutions.

Year 3:

- Fourth COST workshop with bioscience, biocommerce and policy makers.
- Management Committee meeting to prepare final report.
- Fifth COST Workshop and preparation of publication of special journal issue on bio-objects.

Year 4:

- Short-Term Scientific Mission (3 months) of academic leads of 3 (Working Group) dimensions to write scientific report.
- Final international bio-objects conference and dissemination via web, a policy review to the Commission and regulatory agencies in MS.

Exchange of researchers will take place over the whole duration of the Action.

G. ECONOMIC DIMENSION

The following COST countries have actively participated in the preparation of the Action or otherwise indicated their interest: Austria, Denmark, Finland, France, Germany, Italy, Netherlands, Spain, Sweden, United Kingdom. On the basis of national estimates, the economic dimension of the activities to be carried out under the Action has been estimated at 40 Million € for the total duration of the Action. This estimate is valid under the assumption that all the countries mentioned above but no other countries will participate in the Action. Any departure from this will change the total cost accordingly.
In addition, the following non-COST countries have expressed their interest to participate: Canada and USA.

**H. DISSEMINATION PLAN**

**H.1 Who?**

The Action will communicate research results and increase knowledge about ongoing research continually. In order to achieve this, the Action will make use of the insights which will come out of the programme. As the programme aims to counteract an unregulated uncertainty by way of highlighting processes and consequences, it is of great importance that the research is outreaching.

The target audience of this Action consists of several groups who will be targeted in different periods of the Action.

In the first period, the key audience will be social scientists, bioethicists and life scientists who will not only be informed about the activities and results of this Action, but also be invited to actively contribute to it by joining the Action.

At a later stage of the Action, the audience will become more heterogeneous, including not only people exploring bio-objects at the level of theory, but also those dealing with them in their daily lives on a practical level. This group of audience includes policy makers, who deal with bio-objects in their daily lives as policy makers, life-scientists, who make these bio-objects, stakeholder from industry, who trade bio-objects, as well as members of patient groups or of the “lay public”, who might know bio-objects from their encounter with bio-medicine or, such as in the case of GMOs, in the supermarket.

**H.2 What?**

Dissemination methods will be heterogeneous. They will be ‘tuned’ and ‘targeted’ to the specific audiences that the Action seeks to address.
Social scientists, bioethicists, and life-scientists will be “targeted” through the website of the Action, a production of a publicity brochure that informs users about the existence of this Action and which is to be spread in those workshops and conferences that are usually visited by social scientists as well as through the organisation of “panels” that present research related to the Action in international conferences.

At a later stage, the Action’s results will be disseminated to the community of social scientists through publications in journals and an edited volume.

Moreover, the Action’s results will also be communicated to the next generation of social scientists. Indeed, members of the Action will be encouraged to disseminate the results in their lectures and seminars at their home universities and institutes.

In order to disseminate the Action’s activities and results beyond the social sciences, international scientific conferences and workshops will be arranged. The public media, politicians, stakeholders and concerned target groups will also be invited to participate. Press releases will be made in connection to events as well as advertisements in the local media whenever useful. The Action’s website will be dedicated to communication, and promotion of information on ongoing research, seminars, publications and other activities.

Moreover, the Action will prepare its findings in an accessible language and an accessible form. A part from policy briefs published on the Action’s homepage website, the Action will also prepare a small booklet.

H.3 How?

The Action will disseminate its finding, capitalising on existing mediums of exchange. In order to disseminate its findings in the social science community, it will use established conferences, journals, as well as teaching at home universities.
In order to reach stakeholders, policy makers and members of the “lay public”, the Action will use its website as well as the workshops and conference that it will organize. Action members will be encouraged to use their existing links to policy makers, stakeholder and practitioners, to distribute materials provided by the Action and to inform them about the Action’s activities and results.