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The European Group on Life Sciences

Research Commissioner Philippe Busquin

Europe is poised for a bioscience revolution. Progress in the life sciences and biotechnology is opening the way for groundbreaking discoveries and applications in a wide range of fields, including healthcare, agriculture and environmental protection. These exciting advances are helping to develop new knowledge-producing areas at the crossroads of other scientific disciplines, such as genomics, microbial ecology or cognitive sciences, with potentially profound social and economic impacts.

In 2000, when I set up the European Group on Life Sciences (EGLS), I realised that there was a pressing need for intensive debate on the socio-economic and ethical implications of these emerging sciences and technologies. I was conscious that public debate – and media fascination – in Europe was too narrowly focused on genetically modified agriculture which had polarised public opinion and ignored the paradigm changes taking place in science today.

I firmly believe that Europe's policy choice is not 'whether' but 'how' to deal with the challenges posed by this new knowledge and its applications. We need to develop policies that take a forward-looking and global perspective: policies which provide a platform for scientists from all relevant disciplines to debate openly with the wider public the challenges and responsibilities in this promising field.

While debate needs to be oriented towards ensuring the responsible development and application of life science and technologies – benefiting the public while respecting fundamental human values – Europe also has an obligation towards future generations to stimulate groundbreaking research and innovation if it is to achieve its 'Lisbon objectives' of becoming one of the world's leading knowledge-based economies.

The eminent scientists in the EGLS have achieved much more than I could have hoped for four years ago when I welcomed them to Brussels for the first time. As well as keeping me abreast of the latest developments in this sensitive scientific area, they have enriched discussion and public awareness of the major issues in the life sciences and made a strong contribution to the European Research Area.

I am truly grateful for their guidance and assistance.

Philippe Busquin

The EGLS mandate and members

Over the past few decades, progress in the life sciences has led to major benefits in the areas of human health and the environment, and contributed significantly to European industry. At the same time, application of this new knowledge has raised – and continues to raise – a number of ethical and safety concerns in civil society and policy-making circles. At the same time, the gap seems to be widening between the few who know a lot about themselves and their surroundings, and the many who satisfy themselves with an archaic vision of the natural order.

These concerns must be addressed in order to allay public distrust of science and scientific breakthroughs in the life sciences, in particular from the groundbreaking research which may lead to future treatments for debilitating diseases and to new opportunities for Europe's scientists, research community and businesses.

The Group's mandate

The **European Group on Life Sciences** (EGLS) was set up in April 2000 by Research Commissioner Philippe Busquin to meet the European Commission's need for top-quality advice on current and future life sciences and associated technologies.

- One of the Group's main tasks was to keep the Commissioner up to date on what was happening in the fast-moving life science field, providing – through its regular meetings and information services such as publications and websites – advice on imminent or foreseeable developments.

- The second Group's main task has been to enhance dialogue between scientists and the various stakeholders involved in this thought-provoking sector, through its high-level discussion platforms and regular events and publications aimed at addressing major life science issues.

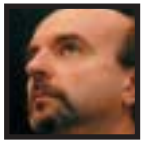
The Group's members

Derek Burke

Professor Burke has been a specialist adviser to the House of Commons Select Committee on Science and Technology (S&T) since 1995. He is a former Vice-Chancellor of the University of East Anglia and former Chairman of the UK Advisory Committee on Novel Foods and Processes. He is a member of EMBO, and has been a member of the Governing Body of the Institute for Food Research in Norwich (UK) and of the Science, Medical and Technology Committee of the Church of England's Board for Social Responsibility. During a research career devoted to the study of the influenza virus and interferon, he notably led the group that cloned the human interferon genes and made the first monoclonal antibody against human interferon. He was Vice-President and Scientific Director of Allelix, Canada's biggest biotechnology company and has served on numerous boards and committees in S&T and engineering.

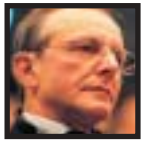
Patrick Cunningham

Professor Cunningham is the Chairman of Irish biotech company IdentiGEN Ltd and Professor of Animal Genetics at Trinity College, Dublin (IE). His research focuses on quantitative genetic theory, the efficiency of livestock improvement programmes, the genetics of cattle, horses and salmon, and the use of molecular methods to study domestic animal evolution and diversity. He has been Director of the FAO's Animal Production and Health Division, visiting professor at the Economic Development Institute, and President of the European and World Associations of Animal Production. He has written two books and more than 200 scientific papers.



Victor de Lorenzo – President of the EGLS

Professor de Lorenzo became the EGLS President in 2002 and works at the National Centre of Biotechnology in Madrid (ES). His research is focused on the molecular biology and genetic engineering of micro-organisms for environmental bioremediation. He belongs to the editorial boards of five international ecology journals, and is a member of the European Molecular Biology Organisation and of the European Environmental Research Organisation. He has served on the OECD ad hoc Committee of Governmental Experts in Biotechnology for a Clean Environment, and as a national delegate and core group member of the European Science Foundation's Standing Committee for Life and Environmental Sciences.



Axel Kahn – former President of the EGLS

Professor Kahn was the EGLS President from 2000, when the Group started, until the end of 2001. He works at Institut Cochin (FR) where he is Head of the Research Unit of genetic and molecular physiology and pathology. His research focuses on genetics, gene therapy, cancer, development and physiology for which he has received several honorary distinctions. He has written four books on modern biology, genes, and ethics, as well as some 400 publications in international journals. For nine years he presided over the Biomolecular Engineering Committee of the French Ministry of Agriculture. He is currently a member of the French National Consultative Ethics Committee.

Philippe Kourilsky

Professor Kourilsky is Director-General of the Pasteur Institute in Paris (FR), where he is also Associate Professor of Molecular Immunology. He joined the Institute in 1972 and seven years later was appointed Director of its unit for Gene Molecular Biology which is linked to the National Institute for Health and Medical Research. His research mainly focuses on genetic engineering and immunology, including stints at the National Centre for Scientific Research (CNRS) and as a Professor at the College of France. A winner of several scientific awards, he has over 300 publications to his name, including a report on the 'precautionary principle' for the French Prime Minister, and two books. He is a member of the Academy of Sciences and l'Academia Europea.

Ladislav Kovác

Professor of Biochemistry at the Comenius University in Bratislava (SK), Professor Kovác's research focuses on bioenergetics – the study of energetic aspects of life processes using biochemistry, physical chemistry and molecular biology. He is a founding member of Slovakia's Academic Society and the Internationale Akademie Schloss Baruth. He served as Minister of Education and as Czechoslovakia's Ambassador to UNESCO. Between 1990-1992, he was Chairman of the UN Intergovernmental Committee for Science and Technology for Development. He has won many

scientific awards, including the State Science Award in 1985, and written over 150 papers on biochemistry and genetics for international journals.

Anne McLaren

Professor McLaren is Principal Research Associate at the Wellcome/CRC Institute in Cambridge (UK), and Professorial Fellow at Melbourne University's Department of Zoology (AU). Her research covers reproductive biology, developmental biology, and the genetics of mammals. A winner of several awards, she has published two books and around 300 publications in scientific journals. She is active on a number of committees, including the UK Government's Panel on Sustainable Development, the Human Fertilisation and Embryology Authority, and the European Commission's Group of Advisers on the Ethics of Biotechnology.

Christiane Nüsslein-Volhard

Professor Nüsslein-Volhard is Director of the Genetics Department at the Max Planck Institute for Developmental Biology at Tübingen (DE). She was awarded the Nobel Prize for Medicine in 1995 for her work on the genes that control development in the fruit fly. She earned her doctorate in genetics in 1973 at the University of Tübingen. Postdoctoral work followed at prestigious laboratories in Basel (CH) and Freiburg (DE). Before joining the Max Planck Institute, she was group leader at the European Molecular Biology Laboratory in Heidelburg (DE). Her work has been published in numerous science journals and publications, and she has won several awards, including honorary degrees from the universities of Utrecht (NL), Princeton and Harvard (US), and Freiburg.

Nadia A. Rosenthal

Professor Rosenthal is Head of the European Molecular Biology Laboratory in Monterotondo (IT), where she directs the Mouse Biology Programme. She also holds a visiting professorship at the University of Western Australia. Through the Cardiovascular Research Centre at Harvard Medical School (US), she directed a biomedical research lab at the Massachusetts General Hospital focusing on mouse developmental genetics, skeletal muscle formation and specification of cell fate in the embryonic heart, with parallel research on the molecular biology of ageing and regeneration. She has served on many advisory panels and editorial boards, including the *New England Journal of Medicine*, and won the Ferrari-Soave Prize in Cell Biology.

Leonardo Santi

Professor Santi is Chairman of the Italian National Committee for Biosafety and Biotechnology of the Presidency of the Council of Ministers (IT); President of the International Society for Preventive Oncology (US); President of the Technical and Scientific Committee of the Agency for the Promotion of European Research (Rome); and Scientific Director of the Superior Institute of Oncology of the Ministry of Training, University and Scientific Research. He has published more than 250 scientific publications on experimental oncology and oncological pathology, concentrating on lung cancers, occupational tumours, and biological response modifiers. He is also a member of a number of scientific organisations, and is on the editorial boards of international scientific journals.

Jan H. van Bemmel

Professor van Bemmel is Chairman of the Department of Medical Informatics at Erasmus University in Rotterdam (NL) where he is also Professor of Medical Informatics. His research focuses on telematics in health and telemedicine. He has published over 380 articles and books, including two textbooks for teaching



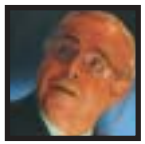

medical informatics in Dutch and English. He is a member of prestigious academies and science associations including the Royal Netherlands Academy of Arts and Sciences, the Dutch Health Council, and the American College of Medical Informatics. From 1998-2001 he was President of the International Medical Informatics Association.

Marc Van Montagu

Professor Van Montagu has served as Full Professor and Head of the Laboratory of Genetics at the University of Gent (BE) and as a part-time professor at the Free University of Brussels (BE). He specialises in cell biology, chemistry, virology, biotechnology, engineering, and microbiology. Along with J. Schell, he is known as the inventor of *agrobacterium tumefaciens* transformation technology, now used worldwide to produce genetically engineered plants. After helping to found the Belgian biotech company Plant Genetics Systems, he served as its Scientific Director and was a Board member. He is a member of many scientific societies, and serves on the editorial board of over ten scientific journals. He has produced over 750 publications and won many prizes.

Hans Wigzell

Professor Wigzell is Director-General of the Swedish Institute for Infectious Diseases and President of the Karolinska Institutet in Stockholm (SE), where he is professor in the Department of Immunology. His main fields of research are medicine, pathology and immunology, focusing on topics such as the regulation of antibody synthesis and of transplantation immunity, immunity in the maternal-foetal context, HIV and immunity, and DNA as a tool in diagnosis and gene analysis. He is an Honorary Life Member of the American Society for Immunology and an elected member of the Danish Academy of Sciences and Letters. He has published more than 560 papers in international journals.



Ernst-Ludwig Winnacker

Professor Winnacker works at the University of Munich (DE) where he is Full Professor of Biochemistry and Chairman of the Laboratory of Molecular Biology. His main fields of research are the molecular biology of DNA replication and recombination, and prion diseases. He is President of the German Research Association and has much experience serving on advisory committees, such as the one established by the German Bundestag to assess the risks and opportunities presented by recombinant DNA technology. He has published his work in over 100 scientific papers and is the author of several books.

Rolf Zinkernagel – former EGLS member

Professor Zinkernagel received the Nobel Prize for Physiology or Medicine in 1996 for discovering how the immune system recognises virus-infected cells. His background includes medicine, microbiology, physiology, pathology and immunopathology. He is currently Head of the Institute of Experimental Immunology at the University of Zurich (CH). He belongs to some 30 honorary or professional organisations and has been on the editorial board of 34 scientific journals. In recent years, he has been promoting actively public understanding of gene technology, animal experiments and science in general.

Also thanks to Tom Blundell for his contribution in the first year of the Group's activities.

Genetics and the future of Europe

6-7 November 2000

Pluralism took centre stage at the forum on 'Genetics and the Future of Europe', held in Brussels on 6-7 November 2000. Several ideas resonated during this pioneering debate between life scientists and civil society. One in particular was that Europe would not be able to exploit fully the promise of genetic engineering unless it succeeded in dealing with society's mistrust and concerns about this area of the life sciences.

Evidently, Europeans feel confused about advances in genetics research. The life sciences have proven their ability to improve the quality of life of citizens in Europe and abroad. For years now, medically assisted procreation, such as *in vitro* fertilisation, has helped the developed world, in particular, fight its battle against ageing populations. But even this relatively straightforward technique raises the ire of pro-life groups.

The prospects of new therapies and medicines stemming from discoveries in genomics raises the stakes even more. That these discoveries may lead to undreamed of progress in fields such as regenerative medicine could be lost amid the objections and media hype, if more is not done to communicate these breakthroughs both sensibly and sensitively to the general public.

But in society today, opening the debate on these issues is, in itself, very sensitive – politically and ethically. Scientists at the cutting edge in the life sciences – as well as the political and economic decision-makers who endorse these new applications – need new forums for pursuing open dialogue with society.

The discussion forum on Genetics and the Future of Europe was the first concrete result of the European Group on Life Science's activities to improve dialogue between scientists and society.

New missions for scientists – selected comments from the event

"Society must increasingly answer questions based on highly complex scientific issues," said Axel Kahn, Former President of the European Group on Life Sciences, Institut Cochin Paris (FR)

"[Science must] stop functioning as a club, with its rites and jargon," insisted Egbert Schroten, University of Utrecht (NL)

"The mission of these committees is not to give a functional answer to the questions asked, but rather to progress gradually towards a consensus on the nature of the stakes," observed Octavi Quintana-Trias, Insalud (ES) and Director for Health Research in the European Commission since 2002

EGLS conclusions on genetics and the future of Europe

Prompted by mounting evidence that Europeans feel alienated by developments in the life sciences, the European Group on Life Sciences (EGLS), acting on Research Commissioner Philippe Busquin's call for more open dialogue between citizens, scientists and policy-makers, organised the meeting 'Genetics and the future of Europe'.

Sessions at the conference covered human health, food integrity and supply, valuing biodiversity, and responsible use of genetics. The two-day event was attended by eminent ethicists, scientists, policy-makers, academics, legal professionals, as well as the standing members of the Life Science High Level Group (the present EGLS).

The general discussions during the meeting focused on:

- Though EU citizens support genetic developments which help to eliminate a problem such as pollution, they need more guidance on genetic discoveries which apply more directly to humans – such as medical genetics: its role in fighting certain diseases, and how to tackle the "spectre of eugenics" – and crop genetics – especially genetically modified organisms (GMOs).
- Europe will not be able to exploit the promise of genetic engineering fully unless it succeeds in dealing with these concerns and manages to integrate them as best as possible into a coherent whole.
- Public mistrust for scientists is a wake-up call to the scientific community and an opportunity to renew the dialogue between science and society.
- While scientists must learn to respect and understand public expectations, values and responses to discoveries in, for instance, GMOs, public opinion should not dictate scientific direction or impinge on research freedom, which is included in the European Charter of Fundamental Rights.
- It is necessary to develop participative methods enabling society to become involved in research policy decisions.
- Health is a typical example of an area where dialogue and transparency are indispensable: patients' associations at the event want to be more closely involved in biomedical decision-making.
- While pluralism enriches debate, national and regional cultures might preclude even minimal European agreement on a basic set of ethical principles in genetics.
- Industrial research can be a driving force for progress in the life sciences, leading to tangible benefits, but some fear that industry's profit motive will hinder, rather than help, the world reach its goals of reducing poverty, combating diseases, etc.
- Discussion also covered the issue of genetic patenting, especially in light of the mapping of the human genome.
- Information agents and mediators play a key role in bridging the communication gap between science and society.
- The dialogue between science and society must enter into the formulating of science policy, as stated in the discussion paper that the Commission has submitted as part of the establishment of the European Research Area.

Delegates concluded that information technology presents a huge opportunity for promoting dialogue between science and society, and should be fully exploited. At the forum's close, Commissioner Busquin – leading by example – held a two-hour Internet session with citizens who asked questions and gave opinions on 'genetics and the future of Europe'.

Stem cells: therapies for the future?

18-19 December 2001

A growing sense of optimism that advances in biological sciences and the development of human stem cells will bring new treatments for previously intractable diseases, such Parkinson's and cancer, dominated the forum on 'Stem cells: therapies for the future?'. But complex ethical issues often accompany new medical discoveries.

The aim of the forum was to launch and encourage an open and informed debate between stakeholders interested in the feasibility and consequences of stem cell research. The two-day conference gave all participants – scientists, technicians, ethicists, lawyers, patients' associations, interest groups, students and teachers, the medical profession, public authorities and civil society – the opportunity to express themselves.

Dialogue was also fuelled by questions and opinions submitted through an on-line forum which Research Commissioner Philippe Busquin personally took part in. This was a hands-on example of how the EGLS helped keep the Commissioner informed on European perceptions of the life sciences, and of stem cells in particular.

The stem cells discussion forum, held in Brussels, 18-19 December 2001, served as a valuable follow-up exercise to the previous year's forum on 'Genetics and the future of Europe', providing further tangible contributions to the life science discourse in Europe. It also helped the Commission in its efforts to survey national opinion on this important subject.

Focusing stem cell research – selected comments from the event

"[We] must ensure responsible and equitable use of new knowledge and new technologies. This can only become a reality through dialogue, notably on a European scale. Today's meeting is an expression of the Commission's will to innovate in this area," said Philippe Busquin, European Commissioner for Research

"Laws protect societal values such as human dignity, on the one hand, but they also protect patients who are to be treated with stem cells or to take part in clinical trials," said Linda Nielsen, University of Copenhagen (DK)

"Stem cells enable the body to replace dying cells... There are high hopes of developing new stem cell-based treatments for a wide variety of diseases, provided we can learn enough about the molecular basis of cell differentiation," commented Peter Gruss, Max-Planck Institute of Biophysical Chemistry in Göttingen (DE)

EGLS statement on stem cell research

The promises and concerns engendered by stem cell research triggers debate worldwide. European citizens realise the significance of these issues and expect guidance to deal with them. The European Group on Life Sciences thanks the European Commission and the European Commissioner for Research Philippe Busquin for arranging such a stimulating meeting on 'Stem cells: therapies for the future?' and thereby contributing to the ongoing European dialogue on this subject.

The current research on human stem cells – either from differentiated tissue or from embryos – is scientifically sound and medically promising, and should be actively developed and supported. Although the use of human stem cells in regenerative medicine is still at an early stage of development, it has the potential to deliver real progress in the treatment of various severe diseases.

The Group agrees that:

- The EU should continue to support research with all sources of human stem cells, including human embryonic stem cells.
- Reproductive cloning should be prohibited.
- Derivation of human embryonic stem cells from nuclear transplants (so-called therapeutic cloning) has not been achieved and appears to raise considerable difficulties. Research into additional strategies to overcome immune rejection is therefore to be strongly encouraged.
- Although the Group respects the special moral status of the human embryo even prior to implantation, it agrees on the use of spare human embryos for the preparation of embryonic stem cell lines. Research on human embryonic stem cells should be carefully regulated, peer reviewed, scientifically sound, directed towards substantial goals, and ethically controlled.
- Publicly and privately funded research should be subject to the same regulations.
- A European registry of human embryonic stem cell lines should be established.

In summary, the Group considers that research on human stem cells offers valuable opportunities in developmental biology and medicine which could revolutionise therapy perhaps on a scale comparable to the introduction of antibiotics.

Towards sustainable agriculture for developing countries: options from life sciences and biotechnologies

30-31 January 2003

Feeding the world's growing population is one thing, but doing it in a sustainable and safe way is another, and a huge challenge facing policy-makers. Major adjustments are needed in agricultural, environmental and macro-economic policy – in rich as well as poor countries – to create the conditions for sustainable agriculture and rural development. This was the general conclusion of the Brussels forum 'Towards sustainable agriculture for developing countries: options from life sciences and biotechnologies', 30-31 January 2003.

Building on momentum generated first at the Rio Earth Summit in 1992, and boosted ten years later at the Johannesburg World Summit on Sustainable Development, the world is getting closer to understanding what is meant by 'sustainable development' – and how it relates to poverty, the environment and use of natural resources.

Through its broad research agenda and development policy, one of the EU's main objectives is to reduce and, one day, eradicate poverty. Sustainable rural development and food security are important features of the Community's anti-poverty strategies. As the livelihood of the rural population hinges on sustainable agriculture, poverty will not be eradicated without a significant modernisation of agricultural production in developing countries.

In its efforts to promote new biotechnologies and knowledge, the Commission acknowledges its responsibility to share this know-how with poorer countries. Its major policy statement, 'Life sciences and biotechnology: a strategy for Europe', clearly stresses the need to put European capacities at the disposal of developing nations struggling to balance the need for higher agricultural yields with sustainable use of natural resources and economic efficiency.

In its penultimate year, the European Group on Life Sciences (EGLS) realised the importance of stimulating open debate on the role that life sciences can play in helping poorer countries tackle these pressing socio-economic challenges.

Spreading sustainable practices – selected comments from the event

"At a time when science and technology are making progress unequalled in history, there remain the undeniable and severe problems of malnutrition and poverty. It would be irresponsible not to assess and discuss how the life sciences and biotechnology might contribute to achieving sustainable agriculture in developing countries," said Philippe Busquin, European Commissioner for Research

"Sustainable agriculture... requires R&D investment, coordination and integration, infrastructure, markets, giving farmers access to technology, and also human resource development. In other words, we need to invest in genotype, the environment, management and people," concluded Timothy Reeves, University of Adelaide (AU)

EGLS statement on sustainable agriculture for developing countries

Ensuring food security is a prerequisite for a stable society. As populations double in developing countries over coming generations, and living standards improve, the demands made on agricultural systems will be unprecedented. With rising demands on useable land, continual improvements in biological efficiency will be an important part of the solution to meet the challenges which lie ahead. The discovery, spread and use of improved, sustainable, affordable and environmentally friendly technologies are therefore an essential part of building the future.

Europe has a duty to contribute to these developments by sharing its wealth of experience, resources and knowledge. The European Group on Life Sciences (EGLS) conference highlighted many examples of how new knowledge in the life sciences can contribute to resolving old problems – knowledge often generated by scientists in and from developing countries. Crop and livestock productivity can be enhanced, pesticide use can be reduced, disease losses can be lessened, and traditional farming systems can be made more productive.

While most of these developments are welcomed for the benefits they bring to farmers and consumers, some are not without controversy, in particular, genetically modified organisms (GMOs). To ensure that benefits from the life sciences spread to populations in greatest need, all stakeholders should help clarify controversial areas and meet legitimate concerns.

And so:

- The EGLS respects the positions of those who challenge scientific developments. Their scepticism is an important part of the verification process insofar as it may bring to the surface the right scientific questions.
- The EGLS sympathises with the right of individual countries and regions in development to make their own judgement on whether to accept or encourage particular technologies.
- There is persuasive cumulative evidence that present GM food is not more injurious to human health than traditional food, and that the potential danger of uncontrolled releases of GMOs is less extensive than postulated by some. The EGLS recommends that a thorough, independent and authoritative review of this evidence, in the specific context of developing countries, be commissioned and published, with due reference to the international regulatory framework in place.
- A number of cases were described where research on genetic modifications of crops led to real benefits, even though some applications are restricted (either by refusal of funding, or by administrative constraints). The EGLS recommends that the EU, in its research and development policy, should not impose unjustified constraints on the generation of new and potentially useful knowledge.
- Believing that knowledge is and should be a shared and freely available commodity – and that it is the most important ingredient in progressive, sustainable and productive agriculture – the EGLS calls for strengthened commitment by the EU to support scientific partnerships with developing countries at national, regional and global levels.
- Such partnerships should foster a flexible approach to intellectual property and should emphasise scientific training as the main pillar of future equitable developments.

Patenting of genes

5 July 2001

Based on discussions between the European Group on Life Sciences and experts from industry, the legal profession, researchers and the European Patent Office (EPO), the European Group on Life Sciences issued a statement on gene patenting. The following is an edited account:

- Patenting of biotechnological inventions, including the application of genes, is important to support research and innovation in biotechnology.

- Universities, academic institutions, and SMEs, in particular start-ups, are the major drivers of innovation in biotechnology. They have become important, and increasingly experienced, users of the patent system.

- Due to increases in international research collaborations, a grace period is needed in Europe, in particular for academic researchers, to put them on the same level as their US and Japanese counterparts. In view of the harmonisation of international patent law, this should be on a 'first to file' principle, minimising large industry's concerns over legal uncertainty.

- The Commission should be supported in its efforts to simplify and speed up patenting procedures and to improve the overall cost-effectiveness of the system. The EPO's changes to its translation procedures are welcomed.

- The discovery of one element of the human body, including the sequence or a partial sequence of a gene, need not constitute patentable inventions (Directive 98/44/EC). Yet an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention if the criteria of patentability are fulfilled.

- Patents on genes do not apply to elements in their natural environment, but only to molecules isolated from the human body or produced by means of a technical process. As such, the phrase 'patenting of life' is misleading and should be avoided.

- The Commission should step up efforts to inform the public about the role and function of the patent system, to counteract misconceptions (e.g. that gene patents provide ownership to those genes and provide patent protection over elements of the human body). Patents do not provide ownership, but merely allow the patentee to forbid others to use the patented product or process for a limited amount of time.

- Shared learning and experience between the different stakeholders responsible for innovation in biotechnology (academics, educators, media, industry, investors, policy-makers, etc.) is a priority. There is an education gap that invites greater awareness for patent law, its objectives and its potential benefits to society.

- Patenting of biotechnological inventions touches upon other national and international agreements and laws which need to be respected by researchers, such as the use of patient data ('informed consent') and genetic resources of other countries. Researchers need to be made aware of, and respect, these agreements

and laws to perform their research in full compliance with these regulations.

- The EGLS has identified a need for stakeholders to explore scientific and legal issues in the context of Directive 98/44/EC, taking into account all possibilities provided under the reporting articles 16 a, b and c. Potential 'dependency' problems related to overly broad patent claims are important in this respect and should be followed closely.

- Genes or gene sequences are likely to be used for different applications (diagnostics, protein coding, etc.) and may code for different proteins which are likely to have different functions (molecular function, cellular component, biological pathways and processes). The application of the product patent and 'first medical use' principles may, therefore, not be reasonable with respect to genetic inventions and could have an undesirable impact on research investment related to further applications or medical uses.

- Case law related to recital 25 of the Directive will further clarify the notion of independence of inventions in cases of partly overlapping sequences.

- In collaboration with the EPO, dissemination and communication efforts should be envisaged, in particular to document rapidly any changes in examination practices following the creation of new case law, especially resulting from state-of-the-art scientific progress. The loop should be closed between advances in scientific knowledge, development of case law, and guidelines used by examiners of patent applications, with all relevant information proactively disseminated to a wide audience through, for instance, the Commission's research programmes.

- The opportunities and limitations – especially issues of competition and how best to serve mankind responsibly – associated with the patenting of biotechnological inventions should be clarified and communicated to a wider audience through attractive publications and media channels. This will be the responsibility of all stakeholders and the Commission.

Life sciences communication in the media

9 July 2002

The relationship between science and the media is not always easy. Scientists complain that the media oversimplifies complex issues and sometimes colours scientific matters with distrust and fear. Journalists criticise researchers for their supposed lack of communication skills and will. To help bridge this gap, the Commission organised a meeting – under the auspices of the European Group on Life Sciences (EGLS) – between scientists and media professionals.

Participants from 13 countries looked into ways to establish closer links and identified more effective practices to improve media coverage of scientific progress in a clear and balanced manner. They came up with a range of novel ideas to improve scientific communication, such as creating an EU-wide network of science communicators, and a programme of exchanges to give journalists first-hand experience of laboratory life.

One of the EGLS' missions is to advise Research Commissioner Philippe Busquin on matters concerning life sciences and related policy matters, in particular those touching upon communication and awareness-raising.

The way science is perceived by the public is heavily influenced by the media. The Group, therefore, co-organised this workshop to underscore the constraints, needs and concerns of scientific journalists working in different European cultural contexts. At the same time, it addressed scientists' frustration at the way journalists tend only to write about breakthrough research or controversial topics, such as genetic engineering or cloning.

Some 40 journalists, communication experts and scientists, together with Commission representatives and Commissioner Busquin, participated in the meeting and recommended:

- Launching detailed studies on science communication in Europe.
- Increasing awareness of respective needs and constraints through, for instance, training or temporary secondment of media representatives in labs and research centres.
- Engaging researchers to produce feature articles for the broader public.
- Networking and co-operation of press and information relays.
- Granting career awards and rewards to good communicators in life sciences.
- Sharing resources and experience amongst bioscience specialised media.
- Organising joint communication events on key life science issues across Europe.
- Fostering a more proactive role in the communication process by the research institutions, which should also guarantee the proper scientific behaviour of their research staff with regard to communication.

These contributions helped the Group refine its position on how to turn new biological knowledge into benefits for EU citizens – in particular, by devising follow-up actions in the context of the EU's Sixth Framework Programme for research and via the Action Plans for 'Life sciences and biotechnology' and for 'Science and society'. Both of these Action Plans stress the importance of a sound and transparent relationship between researchers, the media and the public.

European round table on GMO safety research

The public debate surrounding genetically modified organisms (GMOs) has become increasingly polarised and emotive. With convincing arguments raised by advocates and opponents alike, the general public are left not knowing what or who to believe. The European Commission is committed to facilitating informed debate aimed at finding common ground between the various stakeholders.

One such initiative is the 'Round table on GMO safety' which has sought to raise the voice of science in the GMO debate by establishing an ongoing discussion forum on the research results relating to both the benefits and risks. Set up in 2001 under the aegis of the EGLS, and subsequently held yearly, the round table has assembled biosafety researchers, consumer organisations, national administrations, and industry to ensure that up-to-date knowledge accompanies the safe use of GMOs.

9 October 2001

The 2001 round table debated the human, animal and environmental risks and benefits of growing and using Bt maize. In his opening remarks at the one-day event, Research Commissioner Philippe Busquin stressed that a reasonable and scientifically measured compromise must be found between the so-called GMO 'crusaders' and 'radicals'.

"This is also an exercise in reconciling science and society, bringing together scientists and the interested public to discuss the results of research and jointly to outline a future research agenda in a coordinated way across Europe," he noted. During the round table, the Commission published a report on the results of the biosafety research it has supported over 15 years.

18 April 2002

In 2002, the workshops focused on research into the environmental benefits and risks of growing herbicide-tolerant crops. Using the available research, the experts also discussed how growing and consuming such crops might affect human and animal health.

24 April 2003

At the 2003 'Round table on research results relating to the co-existence of GM and non-GM crops', opinions were exchanged between experts from different countries. The scene was set with a short review of the Danish approach to GM crops, followed by the Belgian experience illustrated by a presentation on the co-existence of different agricultural technologies. In the maize session of the debate, the speakers covered several areas, such as gene flow in maize, co-existence of GM maize in Spain, and hybrid seed production in France. During the oilseed rape session, an Italian expert discussed the economic aspects of co-existence, while a German academic outlined organic farming concerns. Other topics on the agenda included oilseed rape gene flow models, how to segregate crops on farms, and strategies for co-existence.

Modern biology and visions of humanity

This boldly named encounter, organised by the European Commission under the aegis of the European Group on Life Sciences (EGLS), draws its inspiration from the notion that science does not occur in a vacuum, and that scientific development is not always synonymous with progress in all its forms: economic, social, political, etc.

22-23 March 2004

Modern science tends to take for granted that new knowledge stemming from science and technology will benefit humanity, making it a priority for improving the human condition. Yet, alongside this now largely dominant view of science, other opinions of social history – ranging from the moderately sceptical to the outright pessimistic – continue to compete for public attention.

Sceptics raise questions not only about the use, but also about the risk of abuse of the know-how and technologies derived from the life sciences. These questions – often economic in tone but also moral, philosophical, historical, political and, of course, social – keep in check the pursuit of science for science's sake. Increasingly, life scientists and policy-makers are having to ask themselves:

- How can we assess past, present, and future benefits from the extraordinary discoveries and innovations that have been made in recent times within the life sciences?
- Who benefits from progress in the life sciences?
- Can such progress be harnessed to help diminish the appalling inequalities existing around the world, or are the life sciences too much a part of the system that brought these inequalities about and continues to maintain them?

Encounters such as the 'Modern biology and visions of humanity' event in Genoa (IT), 22-23 March 2004, provide an essential forum for airing these questions and, perhaps more importantly, paving the way for scientific development that will ensure progress which is both socially acceptable and genuinely benefits humanity.

The Commission invited eminent speakers and thinkers, including the members of the EGLS, from around the world to stimulate debate on a range of topics organised around four main themes:

- Life sciences and the belief in progress
- The challenge and limitations of reductionism in life sciences research
- Life sciences and democracy
- Science fiction: cultural spin-offs from the life sciences

EGLS conclusions of modern biology and visions of humanity

The EGLS is wary of drawing conclusions – tempting as it may be – from an event such as the 'Modern biology and visions of humanity' one. By design, and through effective moderation, the debates during this 'encounter' were open, fluid and candid, making them difficult to round up in a single conclusive statement. Instead, the Group and the Commission encourage all the delegates to adopt this model of free speech in their respective organisations, and to promote inclusive and thorough debate on science and culture in their regions.

With around 150 participants from 24 countries and a wide range of backgrounds – including NGOs, journalists, educators, scholars, scientists and industrialists – the debate was well rounded and revealing. Two main questions underpinned this multicultural and multidisciplinary exchange:

- What differentiates the arts and humanities from science?
- Why do scientists, who make a huge contribution to humankind, thus modifying our vision of human dignity and the common good, have so little an impact on contemporary cultural references?

Outlets for debate

Not unlike a miniature – albeit symbolic – version of the European Research Area, the encounter also provided ample opportunity for participants to mingle and share experiences across disciplines. Among the avenues explored for future collaboration and initiatives to improve science's status in society are:

- Informal networks, such as science graduates from Italy, France, Germany and Poland, committing themselves to promoting scientific awareness in their respective regions
- Religious groups expressing keen interest in opening channels for structured dialogue with European research policy-makers
- Repeated references to the use of theatre to better communicate science – dispelling the myths and misrepresentations – to the public
- A growing case for recognising the social sciences in the thematic priorities of the EU Framework Programmes
- Encouraging television networks, such as Belgium's RTBF, to deliver the science and society message through telegenic scientists to an increasingly TV-conscious European audience

- Following up on interest shown by editors in the UK, Italy and Belgium to amplify the debate through professional publications such as books
- Exploring ways of solidifying links between the European Research Advisory Board (EURAB) and the EGLS to develop upon the debates and issues raised during the 'encounter' in Genoa

More information:
http://europa.eu.int/comm/research/conferences/2004/biology/index_en.html

The conference video can be viewed on the website.

Axel Kahn

Science does not know where it goes, but this is precisely why it goes there. **Axel Kahn**

"Those who, actually, generate the knowledge, acknowledge that we work for society and we must interact with society as that knowledge is translated into benefits for humans". **Patrick Cunningham**

"Science is not the same as technology. Science is about understanding; technology is about making things. Science has zero ethical content and is basically culture-free. Ethics only may arise with the application of science. Neither scientists nor any specialists group should be taking ethical decisions on behalf of society; the issue belongs to the public domain and ultimately it is our political masters who have to take the decisions". **Lewis Wolpert**

"A knowledge-based society is a society which praises learning for all. Learning respects the symmetry of ignorance," said Klaus Ammann, director of the Botanical Garden, Bern University (CH). **Klaus Ammann**

"Life is like a theatre play. It can be described in every biochemical reaction, exactly as the play itself results from backstage arrangements, light and sound work, stage setting, dressing and text declamation. But this does not mean that all these elements would bring Shakespeare back to life, nor would the functioning of the brain reveal the secret of human thought". **Lewis Wolpert**

Lewis Wolpert – Klaus Ammann – Patrick Cunningham

The Legacy of the **EGLS**

by V. de Lorenzo

What has been done

The Discussions Platforms and the focused **Workshops** have been the most powerful and visible instruments to implement the EGLS mandate. Every feedback from interested parties following the celebration of these events indicated that they did hit the targets, as their conclusions evolved into working documents to guide important policy and communication decisions at the EC level and much beyond. Furthermore, these activities have functioned also as catalysts of many other stakeholders meetings on the same or similar topics held at local levels, helping to foster authentic debates among groups who had hitherto never discussed such a controversial issues in an structured and informed fashion. But this was not all. A less public but extremely useful vehicle for materializing the EGLS mandate has been the regular production and communication to the Commissioner Cabinet of **notes of early warning** on up-and-coming matters likely to demand a quick reaction when and if becoming of public domain, as well as on LS-related issues likely to have an impact on the political agenda. The list of topics reflects the diversity of emerging challenges: *the use of transgenic animals in medical research; the cost of regulation, the need for creation of a European Fund for life sciences research, repair and maintenance of the infrastructure of the science base in Europe, the escalating links between environmental pollution and human health, the influence of biotechnology on the position of the (chronically) ill and the handicapped, the legal and ethical consequences of the storage of genetic data in electronic patient records, the international accessibility to virtual tumour databanks, cloning for babies (i.e., reproductive cloning), mood - enhancing drugs, the growing importance of non-molecular biology in LS research, the contribution of the new member states to science and science policy of the European Union.*

A candid comment on *what has been* done could not be complete without referring to a myriad of informal contacts, meetings and encounters between members of the EGLS and the local science policy authorities and researchers which have frequently hosted regular meetings of the group in their premises, particularly in Granada, Rome and Dublin. The discussions with members of the EURAB advisory Committee as well as encounters with members of the European Parliament are indeed worth to mention, as they have resulted in fruitful communication lines likely to bear fruit in future developments.

The challenge of having a productive debate

What the EGLS has found out from in getting involved in the organisation of the discussion platforms and workshops, in the production and discussion of early warnings to the Commissioner and in the multifaceted contacts with science policy stakeholders? The first is the realization of how complex it is to set up the debate itself. There is an intrinsic difficulty in the Western scientific culture to give weight to angles of a certain problem which do not come exclusively from science and the scientific realm. Similarly, there is a difficulty in most social systems of values to move from pre-conceived positions if they are at all confronted by scientific developments. Gone are the times in which the value of scientific research was self-evident to both decision-makers and society at large. Unlike the times of Enlightened Despotism, were non-democratic rulers could decide on promoting an specific scientific field guided just by curiosity or intellectual challenge, reality is that political leaders are accountable for the decisions they make with public expenditure. Their decisions, including scientific policies, are increasingly subject to a public scrutiny. This imposes an objective pressure (and concern) to pursue the social

acceptance of the new technologies as a pivotal aspect of any decision making in R&D. There is a convergent learning process in this respect. Scientists have to live with the fact that decisions with social implications cannot be made on the only basis of the hard data that experimental science produces -as societies perceive such knowledge with standards and beliefs which are not solely based on rationality. But on the other hand, societies and public opinions have to comprehend that the main strength of modern science -as it has developed since the Renaissance and the Enlightenment, is the capacity to modify views and opinions in light of new data. Productive debates are possible when both sides are ready to change the initial stands in view of new arguments and new results. The period of time spanning the EGLS mandate has witnessed many good steps in that direction, but there is indeed still a long way to go.

The discussion platforms were original in several ways. First an equal amount of time was given to presentations and discussion. Second, each session had there three speakers – one to describe the science that had been done, one to outline possible future developments, and one to discuss social and ethics issues that might arise. Third, the 600 participants were drawn from a variety of backgrounds – from science, from government agencies, from the European Commission and Parliament, and from civil society, including those opposed to the introduction of the new technology. All were free to speak.

Addressing a new generation of scientists

The notion of European Research Area launched by the Commissioner Busquin has raised a positive wave of expectation within the scientific community of our Continent. The possibility of accessing national Research plans and funds for investigators from all countries, the stimulation of networks and Centres of Excellence and the creation of vehicles to target large-scale trans national projects create new scenarios for unfolding the potential of European science. But having the scenario is not enough. We need actors. To this end, scientific research has to be recreated as a noble, exciting and professionally attractive activity for the new generations of Europeans. The growing shortage of early scientists to enrol in PhD Programs and to continue a career is evidence that needs no further demonstration. The issue of creating vehicles by which young talent is channelled into scientific research is thus a major challenge for the future of our continent. Innovation and inventive ability is linked to a young age, we cannot afford losing such a resource. Such channels should ensure not only the access of *peripheral talent* (i.e., individuals from less developed European regions) to frontline Research. They must also stimulate young individuals to discover the *excitement* of science and Research as the frontier of knowledge, for which one's lifetime and efforts are worth to spend. The shortage of young talent may be directly linked to the emphasis that has dominated research policy world-wide, on business, application and market-oriented scientific efforts. The desire to have excellent scientists work on problems that the public or the industry considers relevant and important has always been around in the late history of science. Yet, that key applications are the result of much earlier basic research is a truth which needs little explanation. Top science can never compete for young talent if money is the only issue. The use of research results to secure market shares and maximise profit cannot constitute in itself a sufficient attraction to the imagination of the younger generation. Creativity, excitement and *the challenge of discovery* can. There might be a second aspect to the disenchantment of the young people with Life Sciences research and Biotechnology, and it goes with our underestimate of their ethical sensitivity. The younger generations have surely much greater concern than their parents had for the extensive implications of research and for the inter-relations of living systems, ecosystems, populations and wider

equilibria. What seems to be often rejected among the young is the vision of the engineer who linearly modifies one thing to maximise one product, irrespective of external consequences. And, correspondingly, the growing mistrust of University curricula which are themselves far too linear, specialised, and hardly ever allow a more integrated view of related areas of knowledge. It would be important that the access of young talent to frontline European Research becomes one of the trademarks of the ERA. This has chief consequences for the way Research is conducted in many Centres and Universities and may certainly find opposition from traditional Academic Institutions (and perhaps specific member countries). However, pushing through the notion of merit-based, equal opportunities to young scientists for accessing and developing socially accepted Research careers throughout Europe is a must if we are to have a significant presence in a globalized world.

Outlook: dealing with the boom of biological data

A final Workshop has been planed in Brussels on *Future Challenges for Life Sciences Research*, which is expected to provide a grand finale to the Group as long as it will help to identify the current frontiers of knowledge in the various fields and be of assistance for positioning European efforts within the international landscape of Life Sciences. The years that the group has worked together have continued witnessing extraordinary discoveries and scientific advances which will keep on impacting our societies and will demand dedicated debates as much as considerable investments prior to their conversion into usable technologies. Needless to say that research in ***reproductive technologies*** and *regenerative medicines* are advancing at an accelerated rate which will increase the hopes of many, along with the multi-sided concerns of perhaps others. We have seen also a growing attention to *infectious diseases*, both those known -but re-emerging again with new strength, and those resulting from novel viral or bacterial agents. The renewed interest in infections is not alien to the mounting international concerns on biosecurity -likely to grow in years to come. But we have seen also a motion worldwide towards *white biotechnologies* as well positive indications of a change in the so far prevailing mood in respect to *genetically improved food*. In addition, we observe the development of truly emerging fields which need not only an early awareness but also an early engagement of European capabilities -if we are to became the best knowledge-based economy in the world.

For instance, the ongoing conquest of the *global genome* made possible by the massive DNA sequencing efforts and capabilities of the most advanced countries -but not yet matched by any significant European effort, will result in the ownership of massive genetic resources of the planet by the few who get there first. In the absence of decisive and immediate action, Europe risks being massively and definitively excluded from the social and economic benefits derived from the access to a large proportion of the biological diversity on Earth. The other side of the same coin is the whole of approaches to reshape or even create life forms from scratch in order to endow them with predetermined properties (not alien, of course, to countless possible applications), which is generally termed *Synthetic Biology*. This area of research integrates, without any barrier, knowledge from traditionally remote areas of information such as computer science, *wet* Biology, electronic circuitry and sophisticated chemistry. It is increasingly clear that much of our future as sustainable societies will depend on our ability to reduce industrial wastes and to come up with cleaner technologies and industrial processes as well as renewable energy sources. *Synthetic Biology* paves a way to produce cheap energy (H2), generate electricity from biological processes and to replace progressively physico-chemical industrial methods by environmentally friendly alternatives. The upcoming interfaces between *Synthetic Biology* and *Nanotechnologies*

will have a tremendous influence in our societies and our economies. Such impact will not be devoid of -yet again, ethical angles and social debates. But in the meantime, much of the intellectual property in the field is not in Europe, thus creating a future scenario of extreme technological dependence which needs to be clearly balanced.

Finally, it is clear that we enter an epoch of *trans-kingdom genomics*, in which humans are not seen as isolated entities but as realities framed in a wider landscape of molecular interactions with biotic and abiotic partners. The whole of the biological world is governed by the same rules than the rest of the Biosphere and, therefore, it makes no sense to separate health from food and the environment. The possibility of addressing such complex interactions at the level of whole cells, whole organisms and even whole communities is just emerging through the field of *Systems Biology*, which is bound to bear extraordinary fruits for health, food and sustainable development in the near future. There is thus is a solid basis, much clearer in recent years, to tear down traditional walls between scientific disciplines, as long as modern Genomics is exposing the shared molecular rules which govern the whole of the biological world. There is a considerable social value as well in *Systems Biology* as it poses for the first time the problem of understanding Life-related phenomena in its wider context as an approachable scientific question. This trend is not a mere science-push phenomenon, as the recognition of *Systems Biology* in the University teaching, in the media, in science popularisation etc. will probably put some balance to the extreme-reduccionist approaches which have often alienated so many people -and much young talent away from Experimental Biology.

As civil societies grow stronger in our continent, these fascinating developments will only be applicable as long as they are also socially viable. Prof. Patrick Cunningham, one prominent member of the group, put it recently in black and white: we may be growing closer to request a third layer of viability for new science-based technologies. First, it was the assessment of health-related risks; then, it was the evaluation of environmental impact. And now, will appraisal of social acceptance be the next demand which will check science and technology from expanding only at its own gear? Are we ready to pay the costs of regulating research within a global world and economy? The EGLS leaves these questions open with a feeling of *mission accomplished*, but also encouraging our successors to engage more and more into structured discussions to shed light on future challenges. ■

Conclusions of the European Group of Life Sciences (**EGLS**) on the future of life sciences research

As Europe heads decisively towards a competitive knowledge-based economy, scientific research is growing as one of the ultimate pillars of our viability as a sustainable society. Modern life sciences have brought about immense expectations for improving health, agriculture and the environment, and have opened new avenues for key industrial sectors such as energy production, chemical engineering and the development of new materials. Yet these advances need to develop in parallel with an adequate level of social acceptance which should make scientific and technical progress compatible with the diversity of cultural expectations and value systems that we enjoy on our continent.

The one lesson to emerge after a decade of controversies (GM food, stem cells, reproductive technologies...) is that research, development and innovation can hardly prosper in the face of social opposition to science. Citizens' demands for greater control over their taxes and explanations of how they are spent sometimes come as an unwelcome surprise to scientists traditionally educated in the culture of pure, curiosity-driven research. We are convinced that the way forward is not to avoid or to disguise the debate over modern life science research, but to promote a structured and informed discussion among all stakeholders of any given challenge – those already existing and those still to come. Stakeholders' meetings have been one of the trademarks of the EGLS, and we believe that this format could inspire new ways to raise support for science and, ultimately, to make the Lisbon dream a reality[1]. One of the principal elements of such a debate is to explain what areas of modern scientific endeavour in the life sciences are likely to yield benefits to our societies either directly, in the form of products and services, or indirectly through the general economic development associated with science-based technologies.

But this is not all. The current status of the life sciences widely transcends economic interests and mere material well-being. New knowledge provided by the life sciences about the organisation and function of the nervous system and about animal and human behaviour – both individual and social – may be of crucial importance in correcting centuries-old prejudices about human nature and social dynamics. As such, the achievements of the life sciences may become instrumental in understanding and finding effective solutions to the most serious problems of our times: personal dissatisfaction, religious fundamentalism, interethnic and intercultural conflicts, terrorism and the ensuing global threat to human survival. In line with the rich European cultural tradition, it may be a vocation for European life sciences, and European science in general, to assume a leading – and pivotal – position in this endeavour.

As a contribution to this goal, what follows is a collection of scientific challenges which, as developed societies, we will have to face in the immediate future, and which could help to shape the European research agenda in the coming years. Most of these issues were recapitulated at **the final meeting of the EGLS in Brussels on 28 September 2004 (Workshop on Future Challenges for Life Sciences Research)**.

- The world's **food supply and natural resources** are under threat from population growth, new diseases and environmental degradation. The 'gene revolution' and agricultural biotechnology are powerful and certainly essential tools for generating sustainable agriculture, increased productivity, new markets for plant-derived

(1) Making the EU the most competitive knowledge-based economy in the world by 2010.

products, and for making developing countries more independent. At a more domestic level, life science research can help European **agriculture** tackle its three main challenges: the shift in economic power away from primary producers; the huge changes needed in agricultural infrastructure and systems; and the effect of trade globalisation and liberalisation that could lead to a 20% to 30% cut in EU agricultural output in the very near future. Issues in this field include: weaknesses in the food system and problems with consumer trust; nutrient losses in some soils (and overloading in others), water/air supply and quality; ethical issues, such as animal welfare; food safety, accountability, transparency and quality; and how best to use advances in technology.

- The debate on **genetically modified (GM) plants** is far from over. Despite past controversies, Europe cannot give up the hope raised by their potential applications in agriculture, environmental bioremediation and plant-based pharmacology. Should the right scientific and regulatory environment be in place, the fields of GM plant-based food, the environmental clean-up using plants as biocatalysts, or their use as factories for the production of new drugs carry a significant promise as cheaper and more effective vehicles for adding new value to traditional agricultural or forestry sectors.

- The fact that 70% of the Earth's biomass and 80% of the oxygen on the planet comes from microorganisms highlights the **microbiological dimension of biodiversity** and its potential for new products and processes. Like the New World explorers of the 16th and 17th century, microbiologists today find themselves at the edge of unknown territory. It is estimated that only 0.1% to 1% of microorganisms can be cultivated by current techniques, such that even if the amount of information obtained thus far presents a highly complex picture of the microbial world, the vastness of microbial lifestyles remains to be explored. This means that further exploring the microbial world is vital for a host of new medical and environmental applications. The role of microbial biodiversity and the interface between genomics and the environment (including the exploration and exploitation of microbial reactions for environmental purposes) stands out as a major area of growth in the life sciences with evident economic interest.

- While the ownership of the information present in the human genome (a mere ~30 000 genes) has triggered all social and political alarms, it is shocking that the factual monopoly of the exploration of the global genetic contents of the biosphere (which is yielding ≥ 1 million new genes per year) by the USA is being left unchecked by Europe. Such an ongoing conquest of the **microbial metagenome** (the whole of all genomes) will mean that massive genetic resources will be owned by the few who get there first. Researchers on our continent have the ability and vision to implement ambitious metagenomic projects on a large scale, but lack funding and appropriate structure. By exploring the wealth of new possibilities present in the metagenome of the microbial world, many challenges relating to our ability to reduce industrial waste and come up with cleaner technologies and industrial processes can be taken up.

- The field of **stem cells** will surely dominate frontline medical research within the coming 20 years in, for example, regenerative medicine, cell and gene therapy, drug development and testing or assisted fertility treatment. While reproductive cloning (cloning for babies) is banned in most countries, cloning to produce stem cells for research, derived from patients suffering from complex diseases, will help to produce therapeutic approaches to those disorders. To use such individualised stem cell lines for therapy on a large scale would not only raise major ethical controversies but would probably be unrealistic on economic grounds. Banks of embryonic stem cell lines derived from embryos donated by patients in

IVF clinics offers a much more likely route to the treatment of serious degenerative diseases. Other ways of overcoming the problem of graft rejection look more promising. Additional areas to watch out for include new sources of oocytes, derived from embryonic stem cell lines, for possible use by sterile adults or homosexual couples who want their own biological children (i.e. generating gametes from their own stem cells lines), as well as using gene therapies and nanotechnologies for improving foetal surgery and medicine.

- Many future advances in medicine rely on what is now basic **research in developmental biology**. One key aspect in this respect is the need to understand both early and later stages of development patterns in different species, and to grasp the principles of biological evolution, such as speciation and the common origins of living organisms. This will help to make sense of the biological mechanisms underlying tissue regeneration and other functions which guarantee the stability of organisms throughout their lives. Along the line, more basic research on stem cells (embryonic and adult) – and on regeneration and growth functions – is needed. One intriguing aspect of the development of most living organisms on Earth is that, at one stage of their life, they become parasites or symbionts (i.e. pregnancy, vegetal roots and fungi, intestinal microflora, etc.). This raises the need to boost fundamental research on interactions between organisms and to develop new models for tackling the molecular interplay between the host and its partners.

- The recent outbreak of SARS and the rampant fear of devastating flu pandemics similar to that in 1918 highlight the fact that the unpredictable risk of **infectious diseases** affecting the weaker sectors of society (children, ageing citizens) could dominate the international scene. Many gaps remain in science's understanding of infections, immunology and other areas of biology, and a boost to research efforts is needed to help fight these pathogens. Developing new vaccines is extremely expensive, partly due to the cost of the regulatory requirements. A fundamental goal is to share research findings and expertise, in particular with developing countries, to improve global health. Transdisciplinary research is needed for this, as well as monitoring and early-warning systems for epidemics and the study of reservoirs for infectious diseases. Laboratory models are helpful but more clinical research is needed.

- The clash of facts regarding the potential benefits of scientific research and the social concerns about their applications results in **regulations which frequently involve a high cost**. Aspirin may have never been commercialised under today's regulations, let alone the smallpox vaccine and other medical treatments which, having been created at a time when there was more trust in science, are now standard. It is clear that over-regulation stifles progress in the life sciences, as well as in the generation of new drugs and the fight against infectious diseases, as researchers and pharmaceutical companies feel deterred by the mounting costs of keeping up with safety demands. The same cost creates an extraordinary burden on the development of GM food. Protecting the consumer, including the consumer's right to choose, is valuable and necessary, but Europe's inclination towards over-regulation unduly inhibits innovation and generates extra costs, in particular in the field of GM-food labelling. It has been suggested that the cost of regulation should be made explicit as a percentage of the price – like value-added tax (VAT) – so that consumers would know what they are paying for and can make informed choices.

- One distinct angle on the challenge of having science and scientific research at the basis of economic development is the **correct handling of intellectual property**. We have moved, in just a few years, from enjoying a scenario of free

interchange of ideas and materials between life science researchers to one of extreme caution to secure any possible rights related to the results of academic investigation. The ongoing paranoia over intellectual property rights often puts in place an unethical barrier to access by developing countries to the benefits of agricultural and health-related biotechnologies. It can also inhibit the emergence of novel applications for seminal (but patented) discoveries, the legal status of which is an effective deterrent for third parties to become interested in the very experimental systems now under legal protection. The molecular revolution in the life sciences, facilitated by unlimited exchanges of vectors, samples and results from the Second World War, up to the early 1980s, may never have the chance of happening again, thus depriving society of many possible benefits. This problem requires careful consideration and creative ways to overcome the present situation.

- Despite the considerable controversy fuelled by animal rights activists, the reality is that there are few alternatives to **animal experimentation** in key areas of research linked to human health. Animal models are still needed in the face of new questions raised by the ageing of the population (e.g. degenerative and metabolic problems) and the emergence of new (mostly infectious) diseases. These models will coexist with the birth and subsequent practice of a more integrative second-generation molecular medicine carried out by interdisciplinary research units, effective training programmes for clinicians in molecular biology, and effective means for scientists engaged in basic research to deepen their understanding of medical practice.

- The recent development of the so-called *omics* biosciences (genomics, proteomics, bioinformatics, metabolomics and the like) is entering a new era in life science research. Our era is witnessing the possibility of having the big *pictures* of biological phenomena instead of just bits and pieces which are sometimes far from reality. The new methods which shape **systems biology** allow biological problems to be addressed from a holistic, rather than reductionistic approach, thanks to the import of procedures for analysing complexity (for instance, network theory) from other disciplines such as physics or computer science. For example, we can start entertaining the idea of a *trans-kingdom genomics*, in which humans are not seen as isolated entities, but share a wider world of molecular interactions with biotic and abiotic partners. Similarly, holistic approaches to farming practices and environmental management can lead to healthier food and sustainable development. In fact, these methodological changes are being heralded in fields such as cancer research, where a shift from reductionism to systems biology is already taking place. But all this cannot happen without a cost: the *big biology* in the future will rely increasingly on interdisciplinary skills, massive datasets, bigger investment, better education and state-of-the-art infrastructure (including maintenance of collections and stocks of genetic resources).

- One of the main pillars (if not *the* pillar) of the new life sciences research to come is **computing power**. Well-documented databases (e.g. databases of referred articles, of genes and proteins for biomedicine and health sciences) are an enormous treasure for the advancement of scientific research. A formal *forward* method in analysing large research databases could be limiting. *Inverse* searching, on the other hand, combines different databases by finding new relationships between data. But that is not all. As the information (as reflected in publications) on many experimental systems grows exponentially, it is impossible for a single human to keep track of all the developments related to a single biological problem. We badly need systems for **automated extraction of information from scientific literature** and their

conversion in a numerical format amenable to massive computing. This requirement will not only oblige researchers to adopt formatted vehicles for describing their results with a coherent nomenclature, but it will also open up fascinating interfaces between structural linguistics and bioinformatics.

- The growing presence of physics and computing in the life sciences is giving birth to a whole range of approaches to reshape or even create life forms from scratch in order to endow them with predetermined properties (not alien, of course, to countless possible applications), which is generally termed **synthetic biology**. This area of research integrates, without any barriers, knowledge from traditionally remote areas of information, such as computer science, wet biology, electronic circuitry, and sophisticated chemistry. We risk not gaining a leadership position in such a pivotal field unless massive resources are channelled into its development on our continent. It is becoming increasingly clear that much of our future as sustainable societies will depend on our ability to reduce industrial wastes, to develop cleaner technologies and to consume renewable energy sources. *Synthetic biology* paves the way to the production of cheap energy (H_2), generating electricity from biological processes, and replacing progressively physico-chemical industrial methods with environmentally friendly alternatives. Once again, such a future is not devoid of ethical angles and social debates. But in the meantime, virtually all intellectual property in the field is going to the other side of the Atlantic, thus creating a future scenario of extreme technological dependence which clearly needs to be balanced.

- The still recent experiences of Nazism and Soviet Communism, which presented themselves as entirely scientific approaches to social organisation, have left us with a certain uneasiness about examining social and cultural trends with the tools of the life sciences. But in reality, the **interface between biological sciences and social sciences** offers great potential to address a number of fresh challenges facing, in one direction, modern cultures and, in the other direction, biological phenomena with a major population component. Among the emerging areas in this regard are evolutionary theory (biological and cultural, including memetics), cognitive biology, sociobiology, bio-politics and bio-pedagogy, which can play key roles in attempting to solve problems, such as terrorism and other issues related to human nature and social dynamics. In addition, sociologists and biologists benefit mutually from simple models amenable to experimentation on key aspects of social organisation and evolution (microbial bio-films, the emergence of communication vehicles, the set up of hierarchies, etc.).

- As a final conclusion, the EGLS wishes to remark that **education** is recognised as the major bottleneck for the future of life sciences research in Europe. Young people's lack of interest in scientific affairs is recognised as an alarming trait spreading throughout Europe, which requires urgent action. Inspiration to tackle this difficult challenge may come from successful schemes for appealing to young talent (i.e. the EMBL Graduate Student Programme), which are a useful reference for the future. Media plays a pivotal role in educating and stimulating citizens, particularly the young ones, in the fascinating life sciences field. As we all know, it is up to young people to make Europe an example for the sustainable existence of an advanced, informed, just and developed society – and any effort in that direction would be good.

V. de Lorenzo, Chairman
(on behalf of the EGLS)

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In memory of Raija Anttonen.

More information

More information

The European Group on Life Sciences
http://europa.eu.int/com/research/life-sciences/egls/index_en.html

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