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Recognizing the true worth of Europe's entrepreneurs



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The Commission's recent initiatives, notably in Better Regulation (*see page 18*), innovation and industrial policy, are bringing about more favourable framework conditions for European business. Member States have prepared National Reform Programmes spelling out their strategies to achieve the objectives of the Partnership for Growth and Jobs, and the Commission will be encouraging and supporting implementation of the necessary reforms. And with the new management team at Enterprise and Industry (*see page 4*), we are working with the business community to help develop innovative, competitive and responsible enterprise in Europe.

But above all we need to find the best ways of leveraging the energy and inventiveness of the largest section of that

community: SMEs. With our new SME policy (*see page 7*) I am making sure that the whole Commission is increasingly focused on the needs of small business. The new approach provides a single coherent policy framework for EU actions in favour of SMEs and puts particular emphasis on more systematic consultation and cooperation with SME stakeholders to involve them in the policy-making process at an early stage. This will allow us to benefit more from their experience and increase their commitment to the process.

Key to the success of SME policy is the role of the SME Envoy, who acts to ensure that SME concerns are taken into account across the Commission and as the main contact point for dialogue with the SME constituency. I have decided to reinforce this crucial function and designated Françoise Le Bail, the new Deputy Director-General at Enterprise and Industry, as SME Envoy, while Maive Rute will continue to anchor the team as Deputy Envoy.

Policies facilitating access to finance for example will have a direct effect on boosting growth (*see page 11*), while local and regional initiatives promoting entrepreneurship will be showcased by the European Enterprise Awards (*see page 12*), but more is needed. Our value systems themselves must evolve to better

foster creativity and risk-taking. Society needs to offer small business every encouragement. If they are to succeed in establishing higher levels of growth through innovation and creating the jobs Europe needs, we need to recognize the true worth of our entrepreneurs. 

GÜNTER VERHEUGEN
Vice-President of the European Commission
responsible for Enterprise and Industry

Growth and Jobs: from strategy to implementation

Heinz Zourek has recently been promoted from deputy to the top post in the Enterprise and Industry Directorate-General. Enterprise Europe talked to the new Director-General about how the organisation is aiming to deliver on the growth and jobs policy.



During the first year of its mandate, the Commission adopted a number of initiatives presented by Vice-President Günter Verheugen. With the main elements of the Directorate-General for Enterprise and Industry's leading contribution to the growth and jobs strategy now in place, Mr Zourek is looking forward to the challenge of achieving its objectives, with the help of his newly appointed deputy, former Commission spokesperson, Françoise Le Bail.

'We now have to deliver on what we have been putting forward. We have returned to centre stage and will have to perform and prove that we deserve this.'

'We have to do what we have promised,' he says.

The work programme is clear and consists of four pillars to support and promote European competitiveness. The first is the Commission's overall commitment to better regulation. Innovation is the second pillar, closely linked with the third, an updated industrial policy. The quartet is completed by a refocused strategy for small and medium-sized enterprises (SMEs).

Responding to globalisation

Mr Zourek admits that the policy is deceptively simple: however, achieving its objectives will be a

major challenge, requiring imagination to orchestrate successfully the collective efforts of the large number of partners involved. However, as he and his colleagues examine the national plans implementing the Lisbon strategy, he adds: 'We have one important feature in our favour. Member States are now focusing very much on this agenda. We are no longer standing alone and preaching to a public that is not paying attention. We have now got a strong awareness of the problem among national governments and other stakeholders.'

He is at pains to stress that the focus on competitiveness should not be seen as undermining certain sections of society or

other policy areas. 'It is not a threat to anybody. We are not looking to be a steamroller that flattens everything to do with the environment, social policy or other considerations. We want an integrated approach to prepare the ground for the sustainable development of our economies and societies.

'Without a sound economic base, you cannot have any other derived benefits in a society. We see this as a response to globalisation and not as a driver. We are not trying to depress working conditions, but to ensure the future of industries,' he explains.

Facing the future

One key input towards achieving that goal is predicting the skills that industries will need in a few years' time and steering the efforts of those responsible for training and education to ensure that these needs are met.

To illustrate the pace of change in today's world and the need for constant adaptation, the Director-General recalls how Commissioner Verheugen recently reminded Commission officials with 20 years' service that when they started they had no computer or mobile phones and would either dictate or write out in long-hand texts which a secretary would then type up. 'If you told a 14-year old that you used to work in an office like that, they would look at you in disbelief,' he says.

The new head of the Enterprise and Industry Directorate-General points out that its responsibilities cover issues of critical importance to our societies, either immediately or in the longer term, which need a highly realistic approach. A clear example of this

is the way pharmaceuticals will increasingly be developed using biotechnology, whether people approve of this trend or not: 'We therefore have to prepare ourselves to be equipped to ensure the same levels of safety as apply to today's medicines,' he says.

Mr Zourek has an equally pragmatic approach towards other aspects of biotechnology, pointing to the range of reactions that greet scientific breakthroughs in this area. In contrast to 'white' industrial processes, notably for treatment of sewerage and waste, where indifference is the norm, he accepts that 'green' products, such as genetically modified food, can arouse acute public hostility, while some 'red' items, including tissue engineering, can also raise sensitive issues. 'We would prefer to encourage this new industry in Europe, so we have to make sure it can find the necessary skills and legal environment. However, there is no point in going head-on into a confrontation,' he suggests.

Better Regulation

Enterprise and Industry has two distinct roles in the Commission-wide exercise to simplify and rationalise European legislation which has evolved over 50 years and can contain varying degrees of inconsistency. The first is to speak up on behalf of business.

As Mr Zourek explains: 'To make a coherent, easy to comprehend and less costly regulatory environment we have to advocate the interests of industry and enterprise, whether we are in the lead on that particular legislation or not. This places us in the delicate situation of having to tell our colleagues handling environmental, transport or energy issues, for instance, that



Deputy Director-General from May 2001 and acting Director-General from September 2005, **Heinz Zourek** was appointed Director-General on 9 November 2005.

He joined the European Commission in 1995 as Deputy Director-General of the Internal Market Directorate-General, where his main responsibilities were free movement of goods and services, public procurement, regulated professions, industrial and intellectual property rights and postal services.

Austrian-born Zourek was previously a member of the College of the EFTA Surveillance Authority created by the Agreement on the European Economic Area (EEA) and Director of the Economic Policy Department at the Confederation of Austrian Trade Unions.

they should look at their legislation if it is overly complicated.

Obviously we must make sure our own house is in order, or we will be forced to shut up.'

However, Mr Zourek notes that national and regional authorities also have a major role to play since it is they who largely fashion the environment in which enterprises must operate. As a practical example, he recalls a recent meeting he attended of regions with legislative powers.

'Everyone was quite aware of how many pages of Community legislation there are. But when I asked ministers how many Bavarian or Walloon regulations an enterprise had to comply with, they did not have a clue,' he says.

For the exercise to be successful, it must be accompanied by an identifiable benchmark for measuring it. 'That is why it is important that we have got a clear indication from the Commission of the direction to take. And we have to deliver, not just for the credibility of the institution, but because if we do not, we will not achieve the Lisbon goals.'

Reaching out

While totally committed to the principle of widespread consultation, Mr Zourek stresses that this should be conducted in a decentralised fashion and that it would be an illusion to believe that everyone's views can be heard on everything. He singles out the SME Envoy as a 'great success story' since the role effectively focuses the relationship of small businesses with the Commission. In fact the function has been so successful that the team has needed to be considerably strengthened, culminating in Vice-President Verheugen's designation of Françoise Le Bail to the role.

In the case of industrial areas such as textiles or automobiles, where the nature of contacts is

Françoise Le Bail took up her post as Deputy Director-General on 1 December, 2005, following a year as Chief spokesperson for the Barroso Commission.

She joined the European Commission in 1977, after a Doctorate in Law and a Degree in Political Science, starting her career in the External Relations Directorate-General, dealing with textiles negotiations and ASEAN countries.

From 1985 to 1989, she was the spokesperson for External Relations Commissioner Willy De Clercq and, from 1989 to 1991, successively a cabinet member and Deputy Chief of Staff for Commissioner Christiane Scrivener, who was responsible for taxation and customs.

In 1991, she returned to External Relations and joined the Directorate-General for Trade in 1997, becoming, in 2000, Director in charge of general affairs and of bilateral trade relations with Russia, CIS countries, the Balkans and, more recently, Mediterranean countries, South and South-East Asia.



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either very general or extremely specialised, he favours the creation of high level groups or special dialogues for specific sectors, bringing together producers, employees, consumers and others to consider the general development of an industry, rather than individual items of legislation.

Alongside consultation, the new Director-General sets great store on the need for effective communication to accompany policy implementation. 'Experience tells us that the earlier and clearer you talk about what you want to do, the more people

can understand and follow you. This does not necessarily mean that they agree with what you are trying to achieve, but at least the dispute will be on the substance, not on rumours.' ■

ENCOURAGING EUROPEAN ENTREPRENEURS



Building a better future for small business

The importance of small businesses can never be overestimated. They are the backbone of the European economy, a source of jobs, new ideas and skills and make a valuable social contribution to local communities. For many years now, the European Commission has promoted specific policies to help create the right environment for these firms to thrive and encourage others to take the same path. Now, it is updating its strategy by weaving the various strands into a single coherent framework and by looking to integrate the 'Think Small First' principle into all EU and national policies.*

The primary challenge facing the Union is to promote economic growth and create jobs so that its citizens may enjoy a certain quality of life and the continent can flourish in the face of global competition. Small and medium-sized enterprises (SMEs) are active in every area of the economy and these objectives can only be reached if SMEs are allowed to thrive.

The Commission intends to ensure that SME-friendly policies rank high up the political agenda. Its latest communication* sets out a clear blueprint

for achieving this by analysing the challenges facing small businesses and offering solutions to overcome them.

SMEs are now firmly embedded in the Union's Lisbon strategy for economic reform with the action taken for SMEs forming part of the national programmes drawn up annually by each Member State government. This ensures greater prominence for SME activities and integrates them into a country's mainstream economic presentation as governments work to provide better regulation, develop a

*Implementing the Community Lisbon Programme: Modern SME Policy for Growth and Employment. COM (2005)551 final of 10.11.2005.

more entrepreneurial culture and nurture a supportive environment for small businesses.

The new strategy is designed to cater for the very different needs of small businesses, whether they be start-ups and high growth 'gazelles' or traditional small family firms. It also aims to reduce the legislative and administrative burdens which hit SMEs harder than big companies and to tackle market imperfections such as limited access to finance and obstacles preventing entry to EU-funded research programmes.

Focusing on entrepreneurs

The Commission has highlighted five areas where it believes more can be done to boost SME policy. At the outset, it is looking to create a climate which will encourage people to start their own business instead of seeking the safety of being an employee. Achieving this means reducing the burden of risk that is inherently linked to entrepreneurship and taking initiatives that will minimise the negative effects of business failure.

At the same time, support needs to be provided to would-be businessmen and women. This can either be through general efforts to increase appreciation of entrepreneurs in society or through more specific measures such as skills training or the use of EU funds to develop the

range and quality of business advisory services.

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Many potential entrepreneurs face their first major hurdles when trying to take over an existing company. To help overcome these, the Commission, at the request of the European Parliament, has launched a pilot project to highlight the knowledge and core competencies that are necessary when a firm passes from one person to another. It will follow this with publication of a report on the many different aspects of business transfers.

Improving market access

Despite the success of the single market, SMEs do not always benefit fully from the possibilities that the abolition of national barriers now provides. This may be due to a lack of information, to an absence of transparency or to complex rules.

Some of these difficulties should begin to disappear during 2006 as new legislation comes into force for the EU's €1.5 trillion public procurement market. This will update and simplify the award procedures by encouraging tenders on-line, while the introduction of new environmental purchasing policies will offer opportunities for eco-innovative companies, many of which are SMEs.

To reduce the high tax costs that are often involved when a company is looking to establish a branch abroad, the Commission is proposing a pilot project to allow SMEs to compute the taxable profits of their foreign branches on the basis of their home state.

The 300-strong network of Euro Info Centres will also be used to encourage cross-frontier cooperation and to facilitate 'match-making' among European SMEs and further efforts to promote business cooperation are planned.

Cutting red tape

The Commission has put in place over the past year a comprehensive better regulation programme, ranging from detailed assessments of the impact of its proposals to simplification of measures such as annual reporting requirements. Because of SMEs' limited resources and expertise, the removal of

SMEs in a nutshell

The **23 million** SMEs in the Union account for **99%** of all enterprises and provide some **75 million** jobs. In some industries – textiles, construction and furniture – **80%** of employment is concentrated in small businesses.

complex requirements should be of greater benefit proportionally to small businesses.

In addition, the Commission has raised the possibility of including specific provisions for SMEs: longer transition periods, reduced fees, simplified reporting requirements, help desks and even exemptions.

The better regulation programme is looking at ways to reduce the complexity of procedures that must be complied with before businesses can participate in EU programmes, especially on research. In parallel, there are plans to revise some of the Union's state aid rules in order to encourage public funding for SME innovation.

Value added tax is one obvious area where small companies can find themselves swamped by paperwork. To minimise this, the Commission is proposing simplification measures such as the introduction of VAT one-stop shops.

The Commission's SME Envoy function has already screened the work programme for 2006 and has identified more than 20 measures which it intends to keep a close eye on since they could have a clear impact on SMEs. These include health and safety at work, consumer protection, evolution of labour law and a market access strategy.

Listening to concerns

If there is one obstacle that is most widely identified by the SME fraternity, it is the difficulty in accessing finance. The Commission has already gone some way towards addressing this by proposing to increase indirect financial support to SMEs in its Competitiveness

and Innovation framework Programme (CIP).

This provides for new risk capital measures for innovative and high-growth companies, while a scheme for securitisation of bank loan portfolios will free up finance for more traditional businesses.

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The Commission is placing increasing emphasis on consultation and intends to make this more systematic and comprehensive through the timely involvement of a wide range of stakeholders in its decision-making. The SME Envoy function reinforces this process by liaising with SME representatives and channelling the interests of small businesses to national and European policy-makers.

SME Envoy strengthened

A transversal unit has been set up in the directorate for promotion of SMEs' competitiveness at Enterprise and Industry to coordinate horizontal aspects of SME policy and provide an enhanced support team for the SME Envoy function. In addition Françoise Le Bail is bringing the strength of her position as Deputy Director-General to the

lead role, while Maive Rute, as Deputy Envoy, will be building on her achievements of the past year.

While the central role of business organisations as a channel for SME views into the EU institutions will remain, the Commission is planning to use the Euro Info Centre network to establish SME panels. This is intended to be a quick and easy-to-use form of consultation to elicit small business reaction to specific policy and legislative initiatives.

The Commission is confident that the integrated strategy it has proposed will help to tap into the huge potential of SMEs to provide growth and jobs. But it stresses that for this to be successful, everyone who has the best interests of small businesses at heart, whether they are in the public or private sector or involved at the regional, national or European level, has a role to play.

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Fuelling growth by facilitating finance

Access to finance, including risk capital, is essential for the growth of innovative small companies. The Commission and the UK presidency recently held a risk capital summit in London to examine the factors which influence the flow of funding for business initiatives. The Commission has also proposed a Competitiveness and Innovation framework Programme for the years 2007-2013 which aims to improve the supply of much needed finance to SMEs.

The London summit was designed to emphasise the importance of risk capital as a driver for a more entrepreneurial Europe. It demonstrated widespread agreement that for risk capital markets to function efficiently, several conditions must be met. Those involved have to be able to benefit fully from the single market in financial services; the exchange of best practice and networking between key stakeholders must be encouraged; incentives should be available to risk capital investors; and the overall entrepreneurial environment needs to be improved.

In 2006, following on from the results of the conference,

the Commission will publish a communication, on *Financing growth – the European way*. This will build on existing initiatives and will focus on how to help the providers of SME finance, such as banks and venture capital funds, benefit more from the Union's efforts to break down national barriers.

The communication will illustrate best practices in public-private partnerships and consider how to develop wider cooperation between SME policymakers, financiers and support providers. It will also examine ways in which EU funding available under regional and innovation programmes can be used to help

companies unable to find the finance on the open market.

Banks continue to be the key source of finance for SMEs, with eight out of ten of those polled in a recent survey (see box) using this route. As a result, the Enterprise and Industry Directorate-General will organise a round table of bankers and SMEs during the coming year. This will consider various forms of financing that are especially important for SMEs and identify examples of best practice.

It will look at the degree of transparency between banks and SMEs on the entire rating process and at new cross-border methods, such as securitisation of bank portfolios, for handling SME debt financing. Also on the agenda will be the use of mezzanine finance (quasi-equity) to support innovation and SME transfers.

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BANKING ON BANKS

- One SME in two cannot successfully complete its project without a bank loan.
- One-third of SMEs surveyed believe it is now easier to obtain a bank loan, but 42% say it is harder.
- Seven out of ten SME managers feel their bank manager is sufficiently supportive of their company.
- Banks are the first port of call for 45% of SMEs when seeking financial advice, while 20% turn to accountants and 9% to external consultants.

Source: Flash Eurobarometer. SME Access to Finance, Oct 2005

Supporting entrepreneurship has its own reward

The European Commission has launched a new series of awards to highlight successful initiatives which local and regional authorities are taking to support entrepreneurship. Nominations will close at the end of May and the first presentations will take place in November.

The European Enterprise Awards have been created to fulfil several functions. They will identify and reward measures that succeed in promoting enterprise and will help showcase examples of best practice which others could emulate or adapt. More widely, it is hoped that they will create greater awareness of the role entrepreneurs play in society and encourage others to take the same path.

In addition to the grand prize which will be given to the entry the judges consider to be the most creative and inspiring entrepreneurial initiative, five separate categories have been created.

Actions that promote a business culture and mindset will be eligible for the Entrepreneurial Trailblazer Award, while innovative policies that promote enterprise and attract investment, especially in disadvantaged areas, will qualify for the Enterprise Support Award.

The Red Tape Reduction Award will recognise measures to simplify administrative procedures for businesses, in particular during their start-up phase and the Investment in People Award will mark measures that improve entrepreneurship education and training. The final category, Responsible Entrepreneurship, will be devoted to corporate



social responsibility and sustainable business practices.

The awards are open to local and regional authorities in the EU-25, Bulgaria, Iceland, Norway, Romania and Turkey. This eligibility extends to cities, towns, regions and communities, as well as to public-private partnerships between public authorities and entrepreneurs, educational programmes and business organisations.

Role models

The winning entries will be selected by an international jury with representatives from the worlds of business and academia, as well as the European Commission and national governments. The winners will gain the benefit of publicity and will act as role models for other local and regional authorities in their efforts

to stimulate a more entrepreneurial environment

Inspiration for the awards came from the Enterprising Britain competition launched in 2004. The first national winner was Sherwood Energy Village, a former coal mining community with a bleak future once the pits had closed. Instead of sinking into despair, the local inhabitants organised themselves by focusing on sustainable development and transforming the area into a renewable energy village which is attracting new businesses and residents.

To be considered for the European awards, entrants will first have to go through a national selection process. The final winners in each category in November will be presented with sculptures made of European beech and bronze in the form of a star, representing society, ecology and culture created by the Spanish artist, Rosa Fuentes.

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 europa.eu.int/comm/enterprise/entrepreneurship/smes/awards/

Is biotechnology a business proposition?

Biotechnology is changing our relationship with the world around us. It is driving innovation in medicine, agriculture and industry. To ensure that this emerging technology can develop its full potential, the Commission is launching a study on its social, economic and environmental aspects. The findings will help to update the Commission's existing biotechnology strategy in time for the Spring 2007 European Council which will examine the progress the Union has made on its economic reform programme.



A relatively new discipline, biotechnology is now firmly fixed as one of the Commission's political priorities, reflecting the belief that, if properly used, it has the potential to be a driving force in a modern European knowledge-based economy. The technology's overall importance lies in the fact that it is a major contributor to innovation and competitiveness in almost every field of human activity.

As such, it can play an important role in revitalising the European

economy and in achieving the wider policy goals of creating growth and employment, and protecting public health and the environment. Equally significant is the fact that the jobs associated with the sector are knowledge-rich and highly specialised throughout the value chain.

While modern biotechnology has contributed to major advances in basic science, there is evidence that various European sectors are not adopting it as

much as had been anticipated. Genetically modified crops are hardly grown in Europe, stem cell-related applications are still at the research phase and gene therapy is not available outside clinical trials.

Comparisons between the industry in Europe and the United States are instructive. Although companies in the former tended to have a late and slow start, the pace picked up in the 1990s and there are now more companies, almost 2,000, in Europe than in

the US. However, the European ones on average tend to be smaller, employ fewer people (94,000 against 172,000), invest less in R&D and generate only half the income (€19 billion) of those in the US (€42 billion).

White, green and red

Biotech-based industrial techniques consume less resources by using less energy and creating less waste, help the environment by reducing greenhouse gas emissions, provide biological substitutes for more harmful chemical processes and have potential for alternative and renewable energy. It is a significant enabling technology in traditional manufacturing sectors and in the production of industrial goods such as biodegradable polymers.

This white biotechnology is part of our daily lives. Enzymes, which help digest materials, are already being applied in many sectors: chemicals, pulp and paper, food processing, mining and consumer goods. In textiles, for instance, they are used for the scouring process which removes the brown, non-cellulose part of cotton, which in traditional methods involves relatively harsh chemical solutions.

The use of renewable biomass in large volume chemical production could make one of the largest contributions to CO₂ reduction. For this to become a reality requires the cost-effective conversion of waste biomass, such as straw or corn stovers, to sugars which are the raw material for fermentation. The necessary technological breakthrough could occur towards the end of the decade.

The most visible form of modern biotechnology in agricultural

processes is the development of genetically modified food – a subject that can arouse strong passions, although recent polls suggest public opposition is not as high as a few years ago. Green 'agbiotech', however, covers a wide range of technologies. It is not limited to the genetic modification of plants and is widely used by Europe's main competitors and trading partners such as the US, India, China and Brazil.

Researchers in Scotland, for instance, have modified elm trees to make them resistant to Dutch elm disease which, carried by a bark beetle, has affected over 20 million trees in the UK since 1970 and millions more across Europe. The researchers transferred anti-fungal genes into the elm genome, leading to the possibility of the trees being reintroduced into their native habitat.

In Spain, farmers are managing to prevent the corn borer from destroying their maize by growing a special variety, now used by 12% of producers, that is resistant to the pest. The innovation has helped to raise farmers' incomes, increased yields and quality and reduced

the country's need for imported grain.

Major advances are also being made on the medical front (*see article on page 16*). Modern techniques are opening up new avenues for the development of innovative and more accurate diagnostics and for the discovery of new drugs to prevent diseases and provide cures. Healthcare biotechnology accounts for the largest number of biotech companies in both Europe and the US. Biotech medicines are estimated to account for approximately 20% of all marketed medicines, and represent 50% of all medicines in the pipeline.

Finance and better regulation

Like many new companies, biotech firms can face cash shortages. In the EU, the sector raises three or four times less venture capital and has access to four times less debt finance than in the US. However, the most critical financial period occurs not at the outset, but after a few years in the business cycle when the basic initial research has been completed and companies are looking to enter the wider testing phase. Just when



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Biotechnology makes it possible to produce cotton with improved fibre features.

they should be taking off, many appear to run out of money.

The Commission's proposed Competitiveness and Innovation framework Programme for 2007 to 2013 is intended to address this by creating a supportive environment for innovative firms and encouraging clusters. Another initiative is the new risk-sharing finance proposal contained in the 7th research programme.



Filling up with E85 - a fuel containing 85% bioethanol

Legislation is the second major problem confronting the industry since the very nature of biotech activities demands a high level of public safety. The Commission and Member States are now examining how EU measures on biotechnology are transposed into national law and whether the regulatory system is effective and does not place any unnecessary burdens on companies. They are also considering ways of improving the overall regulatory system and of helping SMEs negotiate this complex landscape. For example, the renewed pharmaceutical regulatory framework has led, in 2005, to an improved functioning of the European Medicines Agency and, lower application fees and better advice for SMEs.

New study

The analysis being conducted by the Commission's Joint Research Centre will straddle traditional interdepartmental boundaries by examining both the research and enterprise aspects of the emerging technology. Its remit is to carry out an assessment study, which could provide a scientifically sound basis for future decisions, assessing biotechnology's activities and potential against the Union's economic reform and sustainable development goals.

It will focus on modern biotechnology. This includes biotechnologies covering DNA, proteins and other molecules, cell and tissue culture and engineering, process biotechnologies and sub-cellular organisms. It will not cover traditional biotechnology processes that are used in the food industry or for bioremediation.

The exercise has two aims. Firstly, it will evaluate the consequences, opportunities and challenges of modern biotechnology for Europe, taking account of its economic, social and environmental aspects. This would be a main input into an assessment of the life sciences and biotechnology elements of the Lisbon economic reform strategy, helping policy makers to map out a programme for the next five years.

Secondly, it is hoped that an independent study will increase public awareness and understanding of life sciences and biotechnology, ensuring that debate on the pros and cons of the technology are based on fact not fiction.

A separate Commission report, *Life sciences and biotechnology – a strategy for Europe – third progress report and future orientations*, published earlier this year identifies some of the issues that must

be addressed if the aims of the Commission programme adopted in 2002 are to be met.

These include developing skills, supporting research, enforcing the intellectual property system, helping all stakeholders working in biotechnology to network and exchange examples of good practice and building on the recommendations from the Competitiveness in Biotechnology Advisory Group with its representatives from industry and academia.

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 europa.eu.int/comm/enterprise/phabiocom/comp_biotech_intro.htm



Advanced therapies, whether they are gene, cell or tissue-based, have enormous potential for the patients who can benefit from them and the companies which succeed in achieving these medical breakthroughs. The Commission's latest proposal in this area is designed to help both industry and the public, while leaving Member States free to decide whether to allow such research or not.

A clearer way forward for medical advances

One of the most exciting features of tissue engineering is its potential to make the human body regenerate a missing part. In the long run, it may enable people to grow an ear, finger or bone and could prevent thousands of people from an early death because of a shortage of transplantable organs.

This regenerative medicine has already seen the development of treatments for skin, cartilage and bone diseases or injuries. Clinical tests are now taking place on more ambitious

products, such as heart valves, blood vessels and heart muscle tissue, which could soon come on the market.

Tissue engineering shares certain key scientific, regulatory and economic characteristics with gene and somatic cell therapies with their potential for treating diseases ranging from cancer to Parkinson's. They are all highly innovative with enormous market potential. A recent study estimated that while the current worldwide market for human tissue is just €60 million, it could soon grow to €100 billion.

But, precisely because the technology is new, national governments that allow research in this area tend to regulate it in different ways. Some use EU pharmaceutical legislation, others prefer legislation on medical devices and a few, like Spain, Sweden and the UK, decide on a case by case basis.

The resulting patchwork in national treatment over classification and authorisation prevents one item from being made available throughout the Union, restricts patients' access to innovative treatment and

handicaps the sector's overall competitiveness.

Safety and opportunity

The Commission proposal is designed to bridge this regulatory gap by creating a single legislative framework. It aims to ensure a high level of public health, harmonise market access and enable the widespread availability of advanced therapy products, foster the competitiveness of the sector, and provide overall legal certainty.

Its chief merit is that it sets out an integrated European framework for all forms of advanced therapies. This builds on existing legislation and practice, provides technical requirements on quality, safety and efficacy, and sets out detailed scientific and regulatory guidelines.

The proposal would establish a centralised procedure for authorising the marketing of advanced therapy products. This will make it possible to pool the limited scientific expertise that exists in modern biotechnology and for manufacturers to sell their products on the basis of one marketing authorisation. Strict conditions would first need to be

Tissue engineering integrates the sciences of biomaterials, cell biology, biochemistry, biomedical engineering and transplantation to create tissue and organ substitutes. From a few cells, it is possible to simulate environments that allow them to develop into viable tissue.

met, including a complete traceability system for patients and products.

Within the London-based European Medicines Agency, a new committee – the Committee for Advanced Therapies – would be established to assess advanced therapy products as they are developed and to monitor scientific developments in this field.

In addition to the concessions that already exist to encourage research in medicinal products, such as accelerated assessment procedures, the proposal contains two new incentives. It foresees a 90% cut in fees for EMEA scientific advice on advanced therapies. It also suggests a system of early evaluation and certification of products developed by SMEs to help them license their technology to bigger companies when conducting clinical trials.

Respecting ethics

Research using human cells raises serious ethical issues. Whether it should be allowed or not is purely a decision for individual governments, not the EU. The proposal fully respects this and does not interfere with national legislation prohibiting or restricting the use of any specific type of human or animal cells. It simply gives Member States and companies which wish to apply the technology a more stable framework.

At the same time, the Commission firmly believes that human tissue and cell-based products should comply with certain principles. Donations should be voluntary and unpaid and donors and recipients should enjoy anonymity. ☰

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EXAMPLES OF ADVANCED THERAPIES

- Gene therapy: amputation of an arm or leg due to critical lack of blood flow could be prevented by using a piece of DNA to stimulate the proliferation and regeneration of arterial cells.
- Cell therapy: renal cancer may be tackled by removing cells from a patient, treating them and injecting the resulting cell lysate to actively stimulate an immune response against the tumour.
- Tissue engineering: a living skin tissue substitute containing human dermal and epidermal cells can be applied as a patch to venous or foot ulcers, gradually merging with the original skin.



pharmacos.eudra.org/F2/advtherapies/index.htm

Less is more: simplifying legislation in the EU

The European Commission has proposed that more than 1,400 pieces of legislation across a wide range of EU policy areas should be scrapped, codified or modified. The initiative is designed to make European law more coherent, and implementation less costly. But better regulation does not mean de-regulation and will not lower environmental, social, public safety or consumer protection standards.

The simplification exercise involves a rolling three-year programme that forms the latest plank in the Commission's commitment towards better regulation and its overall goal of improving the Union's economic performance. It is tackling the most heavily regulated sectors first – waste, cars and construction. These will be followed by foodstuffs, cosmetics, pharmaceuticals and services with other candidates being added over time.

The final selection of more than 220 pieces of Community legislation with their ancillary texts judged suitable for screening emerged from a careful examination within the Commission and extensive consultation with outside interests of the estimated 80,000 pages of European law that have grown up over almost 50 years.

The Enterprise and Industry Directorate-General is playing a prominent role in the exercise. Not only has it taken a leading role in stimulating efforts throughout the Commission to identify rules that could be simplified, but being in charge

of nearly 10% of all EU legislation, it is carefully screening the many measures for which it is directly responsible.

The objective: a better regulatory environment for our businesses and citizens to strengthen European competitiveness

Simplification's many forms

To be a success, simplification will have to overcome the forces of inertia, reluctance and protectionism that oppose change. In its most straightforward form, it involves the repeal of obsolete, unnecessary or irrelevant legislation. The Commission has identified a dozen items that merit this treatment. For instance, a law dating from 1968 classifying wood according to its quality could be replaced by agreed standards. In addition, future Commission proposals will now include a sunset or review clause requiring legislators

to examine, after a number of years, whether the measures are still relevant.

Through codification, it is possible to turn an original text along with all its subsequent modifications into one single document, reducing the legislative mountain and increasing clarity. EU legislation in certain sectors is constantly updated as new products come on the market. As an example, an original directive on cosmetics which has been amended seven times and adapted on a further 37 occasions could be distilled into a single text, and similar exercises can be carried out in any policy area.

More radical is recasting since the process both amends and codifies legislation. Different legal acts can be merged to maximise their coherence, while minimising duplication and inconsistencies. The technique could be used on the 20 separate pieces of legislation that govern safety and health at work. These impose different reporting requirements on companies. Rationalising them, either through a standard

document or a single timetable, would seriously reduce administrative procedures for companies.

Simplification can also be achieved through greater use of 'soft law' such as co-regulation and standards, set by recognised independent bodies. The 'CE' marking placed on products to indicate that they are in compliance with relevant Community legislation and can thus be marketed throughout the Union is a case in point. There are about 17,000 European standards that apply to millions of items on sale in the EU. Standardisation has been a successful simplification tool by limiting the need for detailed prescriptive Community legislation.

Two other techniques exist. Regulations, which apply directly and equally throughout the EU, can prevent the differ-

ences which may occur when Member States adapt directives into their national law. Greater use of information technology, whether it be in public procurement tenders or contacting the authorities, will also simplify life for businesses and the general public.

Collective exercise


The Commission can only achieve the common objective – the promotion of a better regulatory environment for our businesses and citizens to strengthen European competitiveness – if all institutions wholeheartedly support the strategy and assume full responsibility for their share of the effort. Indeed, while the Commission will exercise its right of initiative to design proposals for simplification, the decision-making, and hence the responsibility to deliver, lies with the European Parliament and the

Member States. They must be aware of the consequences of making future legislation overly complex as it goes through the decision-making process.

National authorities can also play a central role by avoiding gold plating EU measures with extra demands when transposing them into domestic law and by examining their own rules. Surveys indicate that public concerns over unnecessary bureaucracy relate more to national and local measures, than to EU legislation.

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 [europa.eu.int/comm/enterprise/
regulation/better_regulation/
simplification.htm](http://europa.eu.int/comm/enterprise/regulation/better_regulation/simplification.htm)

CARS 21

Competitive Automotive Regulatory System for the 21st century

SIMPLIFYING THE AUTOMOTIVE INDUSTRY

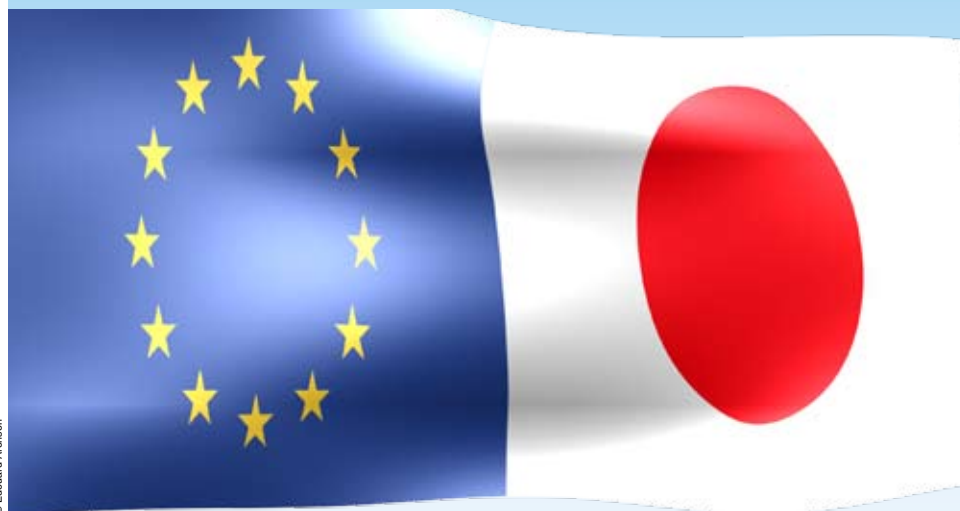
European Union legislation on type-approval of motor vehicles is an obvious candidate for simplification. Currently, EU car manufacturers have to comply with two overlapping procedures before they can market items like fuel tanks, indicators or headlamps. On the one hand, there are 56 EU directives and, on the other, close to 100 United Nations Economic Commission for Europe (UNECE) regulations which apply in the Union as

alternatives to the corresponding EU rules.

The CARS 21 High Level Group has assessed the potential for simplifying EU legislation. It recommends repealing one directive; replacing 38 with UNECE regulations; and introducing self- or virtual testing for 25 directives and UNECE regulations.

The group proposes a set of better regulation principles to

improve the quality of legislation, while minimising the costs of its implementation. It adds that efforts to increase the international harmonisation of motor vehicle rules should be maintained in order to involve key vehicle markets and to extend harmonisation to areas not yet covered.



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EU-Japan: a maturing relationship

The EU's initial concern in its trading relationship with Japan was to ease access of European goods on to the Japanese market. This is still a key aspect several decades later, but the dialogue is taking on another dimension as these major trading partners develop their industrial policy strategies.

Traditionally, EU-Japan business relations were essentially limited to trade-related issues. For the Union, this meant overcoming obstacles, generally different standards and regulations, which prevented European exports from entering the lucrative, but difficult, Japanese market.

The business relationship is considerably more sophisticated now and is seen as a vital ingredient in wider EU-Japan political contacts. At their joint summit in May, Japanese and

European leaders emphasised that 'The ongoing EU-Japan Industrial Policy and Industrial Cooperation should be used to exchange ideas in depth on how to reinforce the competitiveness of the economies of the EU and Japan under the Lisbon Agenda and Economic Structural Reform respectively'.

That cooperation is taking place as both partners are in the process of assessing their wider industrial policies: the Commission with the publication of its industrial policy strategy communication

in October and Japan with its new industry promotion strategy in June following on from the commitment made in 2003 to double foreign direct investment in the country over the next five years.

Industrial Policy Dialogue

The most visible element of the government-to-government industrial policy dialogue is the annual meeting between the Commission's Directorate-General for Enterprise and Industry and Japan's Ministry

EU-JAPAN CENTRE FOR INDUSTRIAL COOPERATION

This unique venture between the European Commission's Directorate-General for Enterprise and Industry and the Japanese Ministry of Economy, Trade and Industry (METI) was established in 1987 as a public non-profit organisation with its headquarters in Tokyo and an office in Brussels.

Its aim is to promote industrial cooperation between European and Japanese enterprises. As part of this objective, it organises management training programmes (Japan Industry Insight and topical missions) and student traineeships (Vulcanus) in companies in each country. These give Europeans and Japanese a valuable insight into business practices in the other's country as well as helping them to develop their language skills. The Centre also offers a business information service for European and Japanese companies which require more knowledge of a market with which they are not familiar. To date, over 1,500 people have participated in the various programmes.

The Centre also supports the annual EU-Japan Business Dialogue Round Table, manages the Alternative Energy Programme and is the coordinator in Europe for the Global Venture Forum.

www.eujapan.com/europe/centre.html

of Economy, Trade and Industry (METI). This provides a forum at director-general level for in-depth discussion of mutual policy developments and industrial cooperation. The latest meeting – in Tokyo on 17 October – was a first opportunity to inform each other of the rationale behind their respective refinements to industrial policy.

The Commission, in particular, is keen to ensure as wide an understanding as possible of its Better Regulation strategy with its emphasis on consultation and impact assessments before legislative or regulatory initiatives are taken. It has already established effective regulatory dialogues with main trading partners such as the US and China and would like to see the same principles operate in its bilateral relations with Japan.

The annual meeting reviews the work of the EU-Japan Centre for Industrial Cooperation (see box) and the activities of the EU-Japan Business Dialogue Round

Table – an industry-led forum that makes recommendations to European and Japanese authorities. It also offers an opportunity to examine the work of several technical groups which have been established to address issues that affect the automobile industry, standardisation, biotechnology (a fast-moving area where the right regulatory framework is essential) and the environmental aspects of enterprise policy.

The Commission and Member States are not alone in promoting European entrepreneurs' interests in Japan. The European Business Council is also a strong representative and produces every year a comprehensive report on the Japanese business environment.

There is considerable convergence of thinking in Brussels and Tokyo on the need for a better identification of promising industrial sectors, for measures to tackle climate change and for a sustainable

environment/economy balance, reflecting the similarity in the challenges faced by both economies. These range from the phenomenon of delocalisation and the emergence of major competitors, such as China and India, to the imperative of developing more environmentally friendly production methods without undermining industrial competitiveness.


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europa.eu.int/comm/enterprise/enterprise_policy/gov_relations/japan_indpol_dialogue/eujapan_political_dialogue.htm

Tackling unfair trade practices

The European Commission's commitment to competition is matched by its determination not to let EU companies suffer from unfair trade practices that might be employed by their international competitors. The Directorate-General for Enterprise and Industry is associated with that for Trade in determining whether such practices are occurring and, if so, which remedies should be put in place.

For international trade to run smoothly, all the players must respect the rules of the game laid down by the World Trade Organisation (WTO). These outlaw certain practices such as giving unfair subsidies to manufacturers or selling goods below production cost in order to undercut international competitors. They also allow WTO members which are injured by such behaviour to defend themselves.

The legislation and procedures which the Union has put in place for its various trade defence instruments are in line with WTO rules, making them clear and transparent in their use. Their aim is to ensure that European companies and industry sectors do not find themselves at a disadvantage because of unfair and injurious practices by their trading partners.

Anti-dumping and anti-subsidy measures (typically in the form of additional import duties) are imposed on dumped or subsidised imports. Safeguard measures are rarely applied since the condi-

tions (an explosion of imports threatening the very survival of industry in the very short term) are much stricter. The EU is careful in its use of such trade defence measures and in the level of the duties it applies, as it

wants to protect industry only in so far as it is injured. In contrast, developing countries are increasingly introducing such measures where it is not always justified, while the severity of the United States' response to unfair trade

EXAMPLES OF TRADE DEFENCE INSTRUMENTS

On 7 July 2003, the European Federation of the Plywood Industry (FEIC) lodged a complaint against imports of Okoumé plywood, which is widely used in the building, furniture and transport industries. This led to the opening of anti-dumping procedures on 19 August. Provisional anti-dumping duties were imposed on 18 May 2004. EU governments made these definitive on 2 November, applying rates ranging from 6.5% to 66.7%, according to the manufacturers concerned.

The Commission opened anti-dumping procedures on 30 June 2005 into imports from China and India of certain footwear with protective toecaps. This followed a complaint from the European Confederation of the Footwear Industry on 17 May on behalf of producers representing a major proportion of total EU production. The investigation is on-going and will be completed within 15 months. If appropriate, provisional anti-dumping duties could be imposed within 9 months (before 30 March 2006).

practices has led to numerous complaints before the WTO. The Commission defends the interests of EU industry when it is abusively or unlawfully targeted by third country measures.

Dumping

Dumping is the most common form of illegal behaviour. This occurs when non-EU goods are sold in Europe at prices below their production costs or more cheaply than on their domestic market. When the Commission receives an allegation from industry that dumping is taking place, it has 45 days within which to examine the complaint and decide whether to launch a formal investigation which must be completed within 15 months.

Price is only one factor in dumping cases. It is also necessary to show that the imports have caused, or threaten to cause material injury to the industry concerned. This could take many forms such as loss of market share or reduced prices for producers. In addition, the complainants must represent at least 25% of the total EU production of the item in question.

The Directorate-General for Enterprise and Industry plays a key role in the proceeding which is led by the Directorate-General for Trade. It is consulted at each stage of the process and uses the detailed knowledge it has built up of individual industrial sectors to examine and define very clearly the particular item at the centre of the investigation to avoid any ambiguity.

The Commission must also apply the 'Community interest test'. This involves assessing whether the wider interests of the Union would be better served by intro-

HELPING SMES

Obviously, it is easy for big companies to lodge a complaint. They have the resources required to prepare a case. But since last year, the Commission has set out to inform small businesses how they too can be protected against unfair trade practices.

A special SME Trade Defence helpdesk has been created to provide quick responses and information and assistance. Complaints tend to be lodged by associations rather than by individual companies. A recent one, tabled by British and Italian, French and Spanish producers, concerned imports of chamois leather originating in China.

The helpdesk is accessible at:

europa.eu.int/comm/trade/issues/respectrules/tdi_sme/contact.htm

ducing anti-dumping duties on the item in question or not. To make this value judgement, it must take into account not only the different views of European importers and producers, but also those of industrial users (downstream industries) and of consumers. Should a significant and unjustified burden on them be identified, it may lead to the non-imposition of trade defence measures.

Selective use

The Union's use of trade defence instruments may attract much media attention, but anti-dumping and anti-subsidy measures apply to just 0.4% of all the goods imported into the Union.

Around 150 measures are in force at the moment, covering all sectors and typically 30 new cases are opened every year.

However, the figure is only the tip of the iceberg. During the same year, officials in the Directorate-General for Enterprise and Industry were consulted on some 200 other cases involving the

complete range of trade defence procedures by colleagues in the Directorate-General for Trade, including reviews of existing measures and anti-circumvention investigations.

China, Korea, Russia, Taiwan and Vietnam tend to be the main targets of trade defence instruments. But they have also been applied to products from developed countries such as the United States, Canada and Australia.

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europa.eu.int/comm/trade/issues/respectrules/tpi_en.htm



Enterprise Europe is evolving

This is the last edition of the Newsletter in its current format. In future, articles will be published initially on the web and material will be selected subsequently for publication in the printed version. This will enable us to provide our online readers with up-to-date commentary on the policy-making at the Directorate-General for Enterprise and Industry, while maintaining greater regularity in our printed publications (the next issue will appear in May 2006, and quarterly thereafter).

Articles will be announced by *Enterprise Europe News Updates*, so make sure you are registered to receive this free email alert service – you can access the online subscription facility at europa.eu.int/comm/enterprise/library/enterprise-europe/

