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June 2007 | 25

SINGLE MARKET

Championing the free movement of goods

Breaking down the remaining barriers

Clearing the road across borders

COMPETITIVENESS

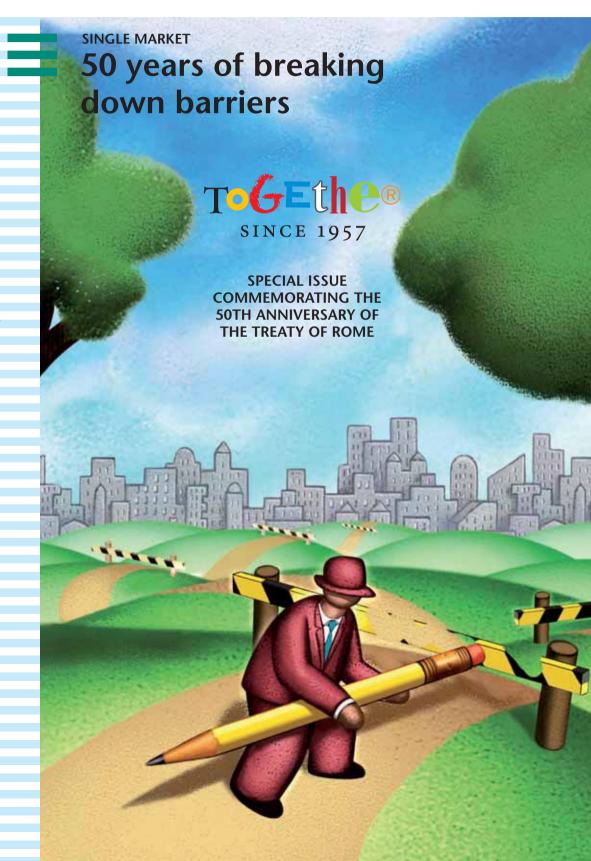
At the summit of European business

INNOVATION

Catching up in innovation

SECTORS

Animal testing: Europe goes alternative





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ENTREPRENEURSHIP

BUILDING ON THE STRENGTHS OF THE SMALLEST ENTERPRISES

The fourth European Conference on Craft and Small Enterprises, held in Stuttgart on 16 and 17 April under the German EU presidency, provided an opportunity to analyse the sector's overall competitiveness and identify its needs. A wide-ranging set of policy priorities was adopted by the participants, addressed to all political levels, to help firms confront the challenges and benefit from the opportunities ahead. The presence at the conference of the German Chancellor and EU President, Angela Merkel, and Commission Vice-President, Günter Verheugen, as well as several ministers from EU Member States, bears testimony to the importance of the high profile event, which attracted over 1,000 participants. Stuttgart is to be seen as a step in strengthening the craft and small enterprise dimension in the Union's modern SME policy.

SECTORS

BRINGING SPACE DOWN TO EARTH

The contribution the space industry makes to our daily lives is far more significant, and tangible, than merely providing us with a better understanding of the universe – important as that is. The sector plays a crucial role in ensuring Europe has a high level of technological and industrial capability and makes its presence felt in areas as varied as environment, transport, communications, humanitarian aid and financial markets. If the EU does not wish to become dependent on others, notably the US, in this area, it must develop a truly European Space Policy. The Commission and the European Space Agency, working together, have shown how this could be achieved and EU governments have recently given their political support to the strategy.

Communication and Information Unit Directorate-General for Enterprise and Industry

European Commission B-1049 Brussels

Tel. (32-2) 29-66549 Fax (32-2) 29-91926 enterprise-europe@ec.europa.eu

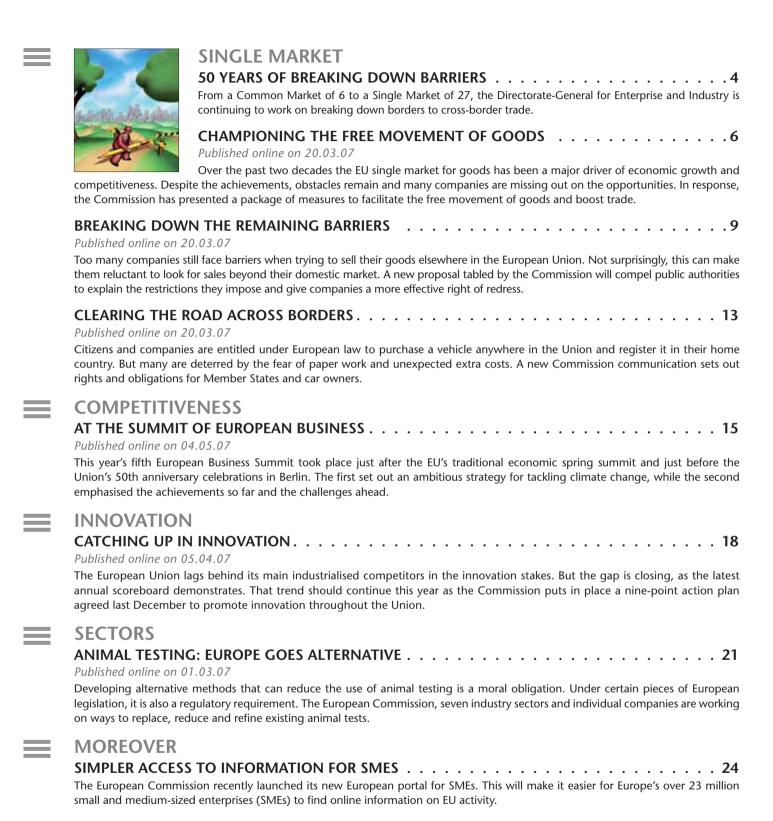
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SINGLEMARKET

50 years of breaking down barriers



From a Common Market of 6 to a Single Market of 27, the Directorate-General for Enterprise and Industry is continuing work on breaking down barriers to cross-border trade.

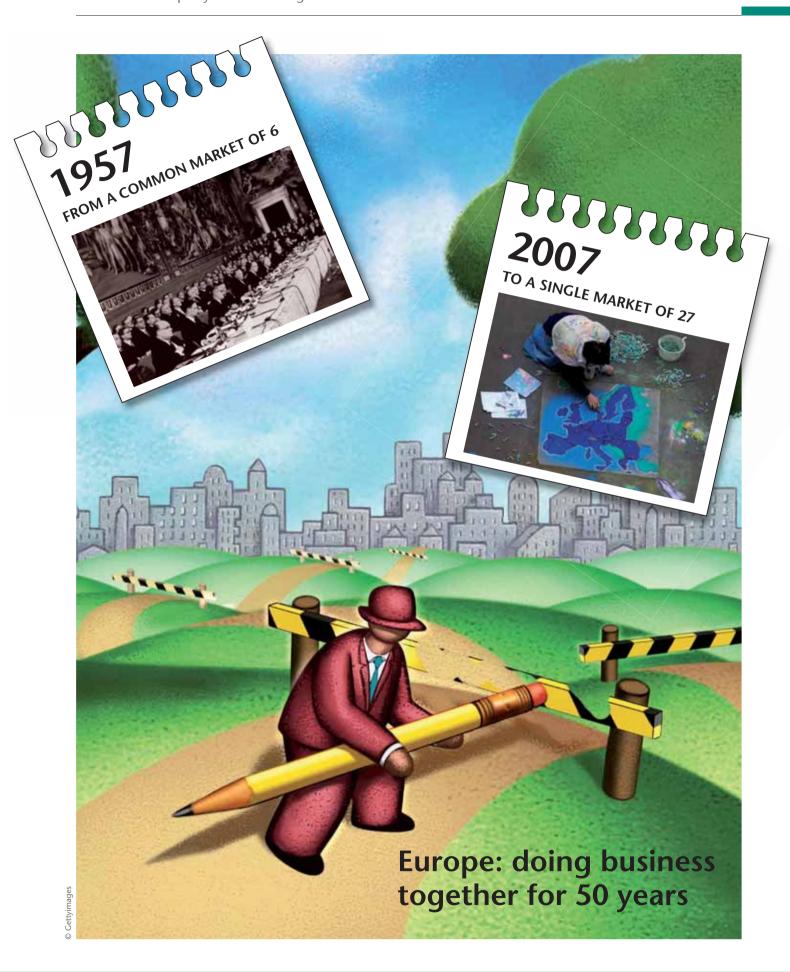


The Common Market established by the Treaty of Rome in 1957 was just the start of a long process of helping trade across borders. Customs and quantitative restrictions were done away with, but bringing a computer across a frontier still involved obtaining a temporary customs licence, while carrying personal medicine could lead to accusations of smuggling.

Border controls were finally lifted 35 years later, following the Single Act, on 31st December 1992. The advent of the Single Market did not however remove all restrictions on access to national markets. Camembert was banned in Denmark, only beer brewed in the German tradition was on sale there, and in Italy just dough made from durum wheat was allowed.

Now the Commission has presented a package of measures to facilitate the free movement of goods and boost trade. The following three articles describe this new package that aims to improve the situation for products covered by Community legislation (the harmonised area) as well as for products for which no harmonised rules exist at EU level (non-harmonised area). It also includes guidance to make it easier to register cars originating in another Member State.

The first article focuses on measures for products that are covered by harmonised European legislation, which represent three-quarters of all internal EU trade in industrial goods. For proposals on non-harmonised goods covered by mutual recognition, see the second article in the series (page 9), while the proposed communication on car registration is explained in a third article on page 13.



SINGLEMARKET

Championing the free movement of goods

The single market for goods is one of the European Union's undoubted successes. Over the past two decades it has been a major driver of economic growth and competitiveness as goods have flowed freely across national frontiers. This has created employment and prosperity, expanded consumer choice and helped EU manufacturers face up to globalisation. Despite these achievements, obstacles remain and many companies, especially small and medium-sized enterprises, are not benefiting fully from the opportunities on offer.



The Commission's latest initiative is designed to boost the free movement of goods by eliminating deficiencies, inconsistencies and unnecessary red tape in the existing rules. This will increase trade and strengthen the confidence of both business operators and consumers in the single market.

The measures proposed will build upon and complement existing legislation in particular in the areas covered by the so-called "New Approach" that was introduced over 20 years ago. Its name comes from the decision to move away from the traditional approach of laying down specific descriptive requirements for products in the legislation itself to a new philosophy that established the *essential requirements* that a product must meet to be considered safe, without prescribing the way in which this must be achieved.

The result is flexible and technology-neutral legislation which provides consumers with safe products and manufacturers with a wider market and the possibility to innovate and keep pace with technical developments. This approach enables manufacturers to export their goods throughout the Union once they have guaranteed that they are safe.

The formula extends to many industrial sectors. These range from the small – electro-technical products, radio/telecoms equipment, medical devices and toys – to the large – machinery, construction products and high speed rail systems. Most items covered by this legislation have the distinctive CE marking on them, which indicates that they meet the requirements of the legislation.

However, over the years differences in interpretation, implementation and enforcement of the existing rules have crept in; along with the sheer growth in the volume of goods traded in Europe, this has meant that the regulatory system now needs to be modernised. The Commission is therefore proposing to update and strengthen the rules and procedures associated with trade in these products. The proposal includes provisions to strengthen market surveillance in Member States, to improve the work of the testing, certification and inspection bodies that carry out conformity assessment and to clarify the meaning of the CE marking for all stakeholders.

Market surveillance

National authorities in each Member State are responsible for the surveillance of goods on their own market. However, not all Member States do this in the same way or with the same level of rigour; partly because of lack of resources and partly because of major changes in the way in which goods have been traded over the past 20 years.

The arrival of e-commerce, the presence of new products on the market and the increasing number of imported goods from outside the Union, all render the authorities' task more and more complex. This increased internationalisation and complexity of commercial transactions make it harder to identify who is responsible in the distribution chain and who should be addressed when there is a problem.



In addition, the intensity of controls and rigour with which national authorities treat law breakers varies considerably and by targeting markets with low levels of supervision, unscrupulous operators can bypass controls, enter the EU market and undermine responsible manufacturers. Closer cross-border cooperation, identifying potentially dangerous products and clamping down on manufacturers or importers breaking the rules is essential to prevent this.

The Commission is proposing measures to do just this, to strengthen internal market control and improve controls at entry points into the Union. The proposal will also improve the traceability of products and clarify the responsibilities of manufacturers, distributors and importers. The result should ensure that only safe products circulate on the market and that unsafe or fraudulent goods are identified quickly, removed from sale in all Member States, with swift action taken against those responsible.

Technical assessments of products

Member States are responsible for selecting the various laboratories, inspection and certification bodies that have the task of checking manufactured goods to ensure that they conform to the EU requirements. For each sector Member States may designate as many bodies as they wish.

There are now over 1 800 of these official bodies competent to carry out the necessary conformity assessment procedures. The sheer number – and the fact that they are private companies operating in a competitive market environment – means that there can be considerable differences in approach, quality and cost. Less scrupulous bodies may cut corners to reduce costs with the risk that certificates may be granted for unsafe products. This is a danger for consumers and confronts bona fide manufacturers with unfair competition.

To remedy this situation, the Commission is proposing measures to reinforce the way in which Member States currently select and monitor these conformity assessment bodies, using accreditation as a tool. This will give the existing informal system of accreditation, which operates to different degrees in different Member States, a legal status that it does not now have, thereby ensuring that the same standards are applied across the board.

The system of accreditation will then have more authority to undertake accreditation services for testing, certification and inspection bodies, so that they can become official conformity assessment bodies.

CE Marking

The easily identifiable CE marking that is visible on many products, for example electric kettles, toys, machines, mobile telephones and computers, is a declaration that the product is safe for its intended use and complies with all relevant harmonised legislation. As such, therefore, it is primarily a mark for enforcement authorities and some confusion as to the meaning has arisen.

Some consumers believe it is a mark of origin or an indication of certification by some kind of authority. Due to lack of knowledge of true meaning, the CE marking on a product does not influence a consumer's decision to buy. Better informed and more proactive consumers would avoid products with no CE marking which would inevitably lead to better compliance in the marketplace.

The Commission wants to tackle this lack of understanding through a Community-wide information campaign to improve the public understanding of the value of CE marking.

In addition to this, the Commission has also applied to register the CE marking as a collective community trade mark. This will give the national market surveillance authorities and competitors greater powers to take legal action against anyone who abuses the marking.

Improving the consistency of the legal framework

Some products are covered by more than one directive and common elements, such as definitions and procedures for demonstrating conformity, are not always treated in the same way. The directives were born at different times over the last 20 years and sometimes definitions or legal provisions are not sufficiently precise, leaving room for diverging interpretations.

This situation inevitably leads to incompatibilities, legal uncertainty, unnecessary duplication and confusion for producers, enforcement authorities and conformity assessment bodies. Beyond the additional costs incurred, manufacturers sometimes find it extremely difficult to understand their legal obligations, let alone apply them. Meanwhile national authorities find it complicated to implement and enforce the legislation. In addition, these inconsistencies can lead to different interpretations in different Member States, which undermines the free movement of goods in the Community.

The Commission aims to solve these problems and to ensure coherence by standardising the various definitions used in the legislation and by clarifying the obligations inherent on the different actors in the supply chain. This will then ensure that the various responsibilities are clearly understood and can be applied more efficiently.

The way forward

The proposals are designed to bring wide-ranging benefits, adding significant value to the internal market for goods, which in turn will generate growth and jobs. Companies will gain from clearer, easier to understand legislation, reduced bureaucracy and red tape, as well as a level playing field. Member States will find improved coordination at Community level, greater means to take action when necessary and more support to ensure that conformity bodies remain competent for their work. Conformity assessment bodies will see increased transparency in the system and consumers will enjoy increased confidence in the system knowing that products bearing the CE marking are indeed safe products.

HELEN SUTCLIFFE, BIRGIT WEIDEL

entr-legal-aspects-intern-markt@ec.europa.eu

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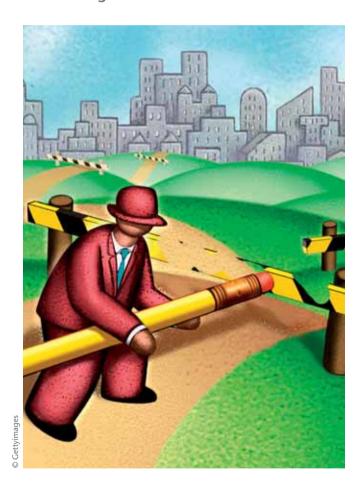


ec.europa.eu/enterprise/library/ee_online/art28_en.htm

SINGLEMARKET

Breaking down the remaining barriers

Too many companies still face barriers when trying to sell their goods elsewhere in the European Union. Local rules on the size, shape and performance of products are often applied in an arbitrary or heavy handed manner. The practice undermines one of the European Union's basic principles: the free movement of goods. Not surprisingly, this can make companies, especially small and medium-sized firms, reluctant to look for sales beyond their domestic market. A new proposal tabled by the Commission will compel public authorities to explain why they will not let a product lawfully marketed in another Member State on to their market. The changes will ensure greater transparency and give companies a more effective right of redress.



economies of scale that come with harmonisation of national technical rules.

But significant obstacles still exist for goods that are not subject to harmonised EU rules. This can create expense for a company which needs to spend time and money identifying and complying with the technical rules in its potential market.

These obstacles have been recognised at the highest political level. Wim Kok, the former Dutch Prime Minister, warned in his 2004 report on the EU's growth and jobs strategy that the free movement of goods in the Union was being hindered by a range of local rules that were often applied arbitrarily. Their removal, he said, should be a priority.

More recently, in June 2006, EU leaders emphasised the importance of an easy-to-apply regulatory environment to strengthen business and consumer confidence in the internal market.

The Commission's latest proposal is designed to remove these obstacles for that category of goods that are not subject to harmonised EU rules. This enables a company that legally places its products on its own domestic market to sell them in another EU country, in many cases without having to satisfy further administrative demands.

Around a quarter of all goods manufactured in the European Union come into this category. They are as

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The EU has eliminated the most common and important technical barriers to the free movement of goods to such an extent that internal EU trade now represents two-thirds of total Union commerce. This benefits citizens through increased choice and businesses through lower compliance costs from the

varied as kitchen kettles, children's clothes, bicycles, furniture, foodstuffs, ladders, mobile working towers and off-road machinery.

New proposal

The new system is designed to provide clear legal procedures for resolving problems that arise without involving companies in unnecessary costs and bureaucracy.

The novelty of the proposed arrangements is that the burden of proof will now fall on a country's national authorities when they insist that imported goods comply with their own domestic standards and perhaps undergo costly modification or testing. They will have to justify on objective scientific or technical grounds why they have taken such action and, if necessary, defend their decision in court.

The overhaul will bring many advantages. The first is simplicity. The draft legislation is contained in just a handful of paragraphs, but provides a clear legal framework.

At the moment, the situations where national authorities can refuse to allow an item that is already lawfully marketed in one Member State to be sold automatically on their territory are determined by the jurisprudence of the European Court of Justice.

This runs to some 300 cases – a wealth of information with which few apart from specialised lawyers are familiar. The latest initiative aims to put all this into practice and make it digestible for enterprises and national authorities alike.

A second advantage is speed. Currently, if a company feels it is the victim of an illegal technical obstacle to trade, it can report this to the Commission. This may lead to a request to the Member State to change its law and allow the free movement of goods in that area. If the dispute is not settled at this stage, it is referred to the European Court of Justice.

The procedure can be lengthy and ultimately bring little satisfaction to companies that suffer from the slow pace of delivery. The new system will empower enterprises by giving them the right to challenge a perceived injustice quickly in national courts. This ensures individual solutions for individual firms

without having to go via Brussels and long drawn-out EU legal proceedings.

The new rules would help to avoid some of the legal uncertainty which can exist when countries implement the principle of free movement of goods in different ways, particularly if technical regulations are overtaken by the pace of innovation as new products arrive on the market.

This should make commercial decisions easier for companies that have difficult choices to make because they are unsure whether their goods can be lawfully marketed in another Member State. Many of them decide not to sell in another Member State, go ahead anyway and hope no obstacles subsequently appear, or accept to incur costs by adapting their goods to local rules.

The dilemma is one that small businesses, in particular, face, since the cost to them of exporting to another EU country can be twice as high as for larger companies. Evidence suggests that small firms, with a turnover of €15 million or less, only export to EU markets that are not overly regulated.

New procedures

Under the proposed system, national authorities cannot simply ban a product for non-compliance with its local rules. They will first have to explain to a company why they intend not to allow its goods to be sold on their market, why they intend to seek the market withdrawal of goods already on sale, or why they may request that products be modified to meet national standards. They will have to justify this on objective scientific or technical grounds, supply supporting evidence, justify the public interest involved and explain possible remedies.

After receiving the written notice, the company will have 20 working days to submit its comments. If the matter is still not settled, it will have the right to appeal to a court or tribunal in its potential market. This will take European law and principles, not just national requirements, into account when hearing the case.

To develop regular and efficient cooperation between national administrations and mutual confidence in each other's policies, the proposal provides for the creation of national product contact points. Their role



EUROPEAN COMMISSION - DIRECTORATE-GENERAL FOR ENTERPRISE AND INDUSTRY

Court of Justice of the European Communities

"Judgment of 20 February 1979, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein, Case 120/78"



Cassis de Dijon: the first drink to lead to a good judgement

This landmark case decided that prohibiting the sale of imported fruit liqueurs with lower alcohol content than the minimum in force in the country of distribution infringed the principle of the

The significant precedent set by this decision has meant that now you can enjoy your favourite drink, or virtually anything else that is available for sale in one country – wherever you are in Europe.

Definitely worth toasting. Cheers!

Internal Market.

Europe: doing business together for 50 years ec.europa.eu/enterprise/regulation/



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To illustrate the huge progress which has been made in removing barriers to the free movement of goods through the principle of mutual recognition, the Enterprise and Industry Directorate-General offered visitors to the 2007 European Business Summit (see page 15) a drink of kir made with the French blackcurrant-based liqueur known as Cassis de Dijon.

will be to ensure enterprises can access the relevant information to challenge technical rules if they believe these are being applied unfairly.

These contact points could be in government departments or professional organisations such as chambers of commerce or even private bodies. They will provide data on the technical rules in force, the authorities responsible for supervising their implementation and contact details of any associations that can offer companies practical assistance.

They will be able to offer advice, but not intervene directly in a case. Given the complexity of modern government, their presence is essential to help companies navigate the system and to stimulate better contacts and understanding between different national authorities.

Economic benefits

Estimates of the costs of administrative red tape vary depending on the product, technical specifications involved and the size of the market. Case studies suggest they can range between 100% and 250% of the annual turnover of the same type of product manufactured by a domestic company in the same

market. Companies specialising in one specific item can find compliance costs reaching between 10 and 15% of their entire annual turnover on a large market.

The proposal must now be approved by EU governments and the European Parliament. It is seen as a practical way to tackle the myriad of technical obstacles that can arise in trade between 27 countries containing almost 500 million citizens, without putting in place costly and time-consuming administrative arrangements.

HANS INGELS

entr-gen-framew-free-movement-goods@ec.europa.eu

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ec.europa.eu/enterprise/library/ee_online/art27_en.htm

SINGLE MARKET ARKET

Clearing the road across borders

Citizens and companies are legally entitled under European law to purchase a vehicle anywhere in the Union and register it in their home country. But many are deterred because they fear they will have to wade through a mound of paper work and be hit with unexpected extra costs. A new Commission communication is coming to their aid. It sets out in clear terms existing rights and obligations for Member States and car owners when registering motor vehicles which originate in another EU country. The information covers the registration procedures involved, value added tax payments and use and transfer of number plates.



The legal situation is clear. One of the benefits of the single market is that motor vehicles may be bought in one country and registered in another. If they meet the necessary standards and have the correct documentation, no further formalities are required.

However, some authorities insist on technical tests, which may have already been carried out elsewhere,

or stipulate that changes have to be made to the vehicle even though it already has a European type approval certificate.

As a result, private citizens and companies are making more and more complaints about the difficulties they meet and costs they incur when looking to register a vehicle in another Member State.

Currently, 20% of the legal cases the European Commission has brought against Member States over alleged violations of the principle of the free movement of goods involve the registration of motor vehicles.

Advice to car buyers

The communication gives an up-to-date overview of the law that applies when a vehicle is either bought or registered in one Member State and then moved to another. It is designed to ensure that national authorities implement the legislation correctly and do not create unnecessary obstacles for vehicle owners.

The different national systems of type-approval which previously existed have been replaced by the EU whole vehicle type-approval. This has applied to most passenger cars since January 1998 and motorcycles from June 2003. The EC certificate of conformity, which manufacturers provide, confirms that the vehicles meet all the relevant European standards. It entitles them to be sold, registered or to enter into service without any further formalities, making registration faster and easier.

Further legislation is currently being processed by EU governments and the European Parliament. Once approved, commercial vehicles, such as buses, coaches, vans and trucks, will be subject to the same system.

Practicalities

No matter where car owners first purchase a new EU type-approved vehicle, they can register it in their home country simply by using the European certificate of

conformity. According to existing legislation, a vehicle is new if it is used within six months from the date of its first entry into service or has less than 6 000 kilometres on the clock.

If an owner has already registered a vehicle in one Member State and then moves to another, the authorities in the new country of residence may only request certain documents. These include a copy of the previous registration certificate, proof of payment of VAT, an insurance certificate and, in certain situations, a roadworthiness certificate.

The communication contains details of the VAT requirements that apply to professional dealers and private individuals and to the status of number plates when transferring a vehicle to another EU country.

In the next few months, the Commission will publish a practical citizen's guide to car registration in the European Union. This is designed to help people who either buy a vehicle in another EU country or move to a different Member State and need to register their vehicle.

HANS INGELS

entr-gen-framew-free-movement-goods@ec.europa.eu

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ec.europa.eu/enterprise/library/ee_online/art26_en.htm

COMPETITIVENESS

At the summit of European business

This year's fifth European Business Summit took place just after the EU's traditional economic spring summit and just before the Union's 50th anniversary celebrations in Berlin. The first set out an ambitious strategy for tackling climate change, while the second emphasised the achievements so far and the challenges ahead. Both themes featured prominently during the two days of discussions involving the business and regulatory communities in an atmosphere that was noticeably more upbeat than in previous years.



Vice-President Verheugen: "We have not yet reversed the trend, but we have achieved a slowing down of the negative trend".

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José Manuel Barroso, the Commission President, speaking on the opening day, captured the mood of the conference when he noted that there was now more confidence in Europe than there had been just two years ago and that the Union was beginning to reap the rewards of the reforms it was putting in place.

Unemployment is at its lowest level for a decade with the prospect of seven million new jobs being created between 2006 and 2008. Economic growth, at 2.9%, is higher than at any time since 2000 and is projected to remain steady throughout the coming year. Europe is also making advances in labour productivity, labour skills, investment and the sustainability of public finances.

But he emphasised that there was no room for complacency. "We still have some way to go if we want to shape globalisation, to become effective actors on the world stage and equip European citizens and businesses for globalisation," he told the audience.

Vice-President Günter Verheugen, the Enterprise and Industry Commissioner, struck the same note when he emphasised to participants that the EU's jobs and growth strategy was gradually helping to establish the right economic environment. Two years after its relaunch, he noted: "We have not yet reversed the trend, but we have achieved a slowing down of the negative trend."

For the first time, the Commission had proposed country specific economic action. Member States had endorsed this initiative and already agenda changes are taking place in national plans. Increasingly, the focus is on education, training, research and innovation.

Better regulation

Mr Verheugen stressed the importance the Commission attached to better regulation, pointing out that "the whole structure and architecture" to achieve this were now in place. In future, no legislation would be proposed without an impact assessment, quality control and scrutiny by an independent board. "We are witnessing a change in culture among European policy makers away from the view that if it moves we must regulate it," he said.

He emphasised the scale of the potential benefits. The average cost of administrative burdens on companies now equals some 3.5% of total EU GDP.

If that was reduced by a quarter, it would boost GDP by 1.4% from 2012 onwards and be worth €150 billion.

President Barroso also emphasised the importance of better regulation and issued a direct appeal to businesses to support the Commission in its drive to cut red tape. "Let me make clear that this is not the exclusive domain of the European Commission. Member States too must roll up their sleeves. As businesses, it is your task to ensure that they do. Don't take 'no' for an answer," he told his audience.

Future challenges

The Commission President pointed to the need to make Europe's markets function more smoothly for the benefit of citizens, consumers and businesses when faced with the speed of economic and social change around the world. To help achieve this, the Commission is reviewing ways to oil the mechanism of the internal market and to remove any obstacles it identifies.

But in the modern world, focusing on internal issues alone is not sufficient. And with trade now a key external element of the Union's growth and jobs strategy, President Barroso underlined the need to deepen economic ties with the EU's main trading partners.

He illustrated the importance of EU/US links and of strong regulatory and standards convergence by pointing out that total US investment in China in 2006 was only one quarter of its total investment in Belgium the previous year - a country a fraction of the Asian tiger's size.

With energy and the move to a low carbon economy now firmly on the EU's agenda, Vice-President Verheugen told the conference that it was necessary to establish the right policy mix that addressed the twin challenges of creating jobs and protecting the environment.

Mr Verheugen, like President Barroso, stressed the need to reform the EU's institutional structure as the Union carries on a serious debate on how to achieve this after the rejection of the draft constitutional treaty by France and the Netherlands two years ago.

"Our system is not up to the challenges of the 21st century. We need Europe to change and to improve our decision-making. We need a combination of economic reform and political reform," he said.

Access to capital

Addressing a session devoted to the financing problems often faced by companies, especially small ones, Françoise Le Bail, the Deputy Director-General for Enterprise and Industry and SME Envoy, quoted from a study by the Centre for Economic Policy Research.

This showed that if EU manufacturing companies had the same access to finance as US companies, value-added growth in EU manufacturing would increase by 0.75-0.94% on a durable basis.

The problems which SMEs face when trying to access finance had earlier been set out by Rudy Aernoudt, the Secretary General of the Flemish Department of Economy, Science and Innovation. He listed the low share of equity capital, to the legal, regulatory and tax barriers that exist, to the lack of seed investors and venture capitalists, and a climate of risk aversion.

In addressing these market weaknesses, Mrs Le Bail pointed out, the Commission has developed two basic responses: a loan guarantee facility and a venture capital instrument. To date, over 300,000 small and medium-sized enterprises (SMEs) throughout the EU, as well as Turkey and Norway, have benefited from these measures.

The potential for helping companies will be even greater in future under the Competitiveness and Innovation framework Programme (CIP). Between 2007 and 2013, the funding available for these financial instruments will be almost doubled to over €1.1 billion, providing resources to assist over 400,000 SMEs.

In addition to increasing the funding available, the Commission has fine tuned the uses of the programme to make them dovetail better with SMEs' needs. Mezzanine financing will be available to small firms during their expansion phase. Cooperation between business angels and venture capital funds is being encouraged. A new securitisation window will increase the capacity of banks and other lenders to finance SMEs by helping them to sell portfolios to investors and eco-innovation is targeted for the first time.

Corporate social responsibility

The importance of corporate social responsibility (CSR) for the business community was emphasised by Maive Rute, the Deputy SME Envoy. It can contribute to the EU's growth and jobs strategy by being a source of innovation as companies develop new products and services to meet society's changing needs.

It can also help to improve public trust and confidence in the corporate world and through employment diversity policies promote integration into the workforce of people from traditionally marginalised groups.

But while the Commission has raised the profile of CSR and the expectations of what business should deliver in this regard, she insisted the concept would remain voluntary and ruled out any suggestion of making it a regulatory requirement.

She also emphasised that CSR is a concept that is valid for all companies, whatever their size. For the past 18 months, the Commission has been working with a group of national experts to pool ideas and experiences on how best to support and encourage CSR among small businesses.*

There seemed little doubt regarding the significance of the issues raised at the summit and the possible extent of their impact. Participants also appeared convinced that an increasingly positive partnership between business and governments will find the necessary solutions.

PETER WRAGG

entr-communication-information@ec.europa.eu

For useful links, visit the article at



ec.europa.eu/enterprise/library/ee_online/art30_en.htm

^{*} The report of the European Expert Group on CSR and small and medium-sized enterprises – Opportunity and Responsibility: how to help more small businesses to integrate social and environmental issues into what they do – was launched on 3 May at an innovative event, the Responsible Entrepreneurship Exchange.

INNOVATION

Catching up in innovation

The European Union lags behind its main industrialised competitors, notably the US and Japan, in the innovation stakes. But the gap is closing, as the latest annual scoreboard demonstrates. That trend should continue this year as the Commission puts in place a nine-point action plan agreed last December to promote innovation throughout the Union.



Two clear themes emerge from the sixth edition of the European Innovation Scoreboard. The first is that the innovation gap between the EU and the US has narrowed for the fourth year in succession. Secondly, national innovation performances within the Union are beginning to converge as new Member States move closer to the EU average.

The trends suggest that the reforms within the Union's growth and jobs strategy are beginning to bear fruit as the European economy becomes more innovative. They also reflect the recent economic upturn the continent has enjoyed, which the Commission believes should be used as a further spur towards structural reforms.

This snapshot of the state of play of innovation in the EU-25 last year emerges from an analysis of 25 different indicators ranging from the percentage of the population with tertiary education to the number of new patents registered. These are grouped into five main families: innovation drivers, knowledge creation, innovation and entrepreneurship, applications and intellectual property.

Closing the gap

Over the past year, the EU has improved its relative performance against the US in almost a dozen indicators. These include new science and engineering (S&E) graduates, who now make up 13 per thousand 20-29 year olds in Europe compared to 10 in the US. The EU also leads in employment in manufacturing industries that produce high-tech goods (7% of total workforce compared to 4% in the US).



However the EU lags behind in other key areas. Venture capital investments in the early life of a company are three times higher the other side of the Atlantic than in Europe. The share of total exports taken up by high-tech products is noticeably higher in the US (26.8%) than in the EU (18.4%) and the US files considerably more patents.

After falling further behind Japan in 2005, the EU has reversed the trend, making up ground lost in the previous four years. The change in fortunes was partly due to a stronger performance in S&E graduates and broadband penetration rate.

Within the EU, significant national differences remain between innovation leaders, innovation followers, catching-up countries and those trailing behind. The first group contains Sweden, Finland, Denmark and Germany. They are followed by the UK, France, Netherlands, Belgium, Austria and Ireland, which find themselves basically on a par with the US.

A third group consisting of Slovenia, the Czech Republic, Lithuania, Portugal, Poland, Latvia, Greece, Bulgaria, Cyprus and Romania are below the first two, but are succeeding in closing the gap through their faster than average innovation performance. The final category, which includes Estonia, Spain, Malta, Italy, Hungary, Croatia and Slovakia, appears to be trailing behind, although the efforts being made now could reap dividends in future. This could be particularly true of Spain, which has increased its R&D budget by 25% three years in a row.

Overall, however, the scoreboard points to greater convergence within the EU as the leaders find it harder to maintain investment in their innovation packages, and those further behind, often starting from a low base, attach a higher priority to innovation policy than in the past.

The report provides innovation information on a regional basis, updating data last produced in 2003. Not surprisingly, regions with the highest rankings, such as Stockholm, Upper Bavaria and Île-de-France, correspond to countries in the innovation leaders group. Two notable exceptions are Prague in 15th place and Bratislava 27th.

Constantly refined since it was first devised, the EU's innovation scoreboard is attracting growing international attention in industrialised countries such

as Israel, one of the world leaders in this area, and Australia, which has declared an interest in being included in its analyses.

The scoreboard reinforces a key message that emerged from last September's communication on innovation: to perform well in the innovation stakes, it is necessary to have a strong all-round performance. Weaknesses in one or more of the five families of indicators can drag down the whole and must be tackled, but not in isolation.

Accelerating the process

As the EU's innovation policy becomes more sophisticated, the emphasis is shifting away from assessing what can be done to improve innovation performance per se to ways in which imaginative breakthroughs can be used in practice to achieve societal goals.

This can be seen from the agreement at last December's Competitiveness Council. This acknowledged the critical role that innovation can play for Europe to respond to the challenges and opportunities of the global economy and its important contribution to the EU's growth and jobs strategy.

To accelerate the process, the Council agreed a ninepoint strategic priority action plan, which is currently being put into practice.

The creation of a European Institute of Technology is arguably the plan's flagship. Commission President José Manuel Barroso told the European Business Summit in mid-March that this could be operational by the end of the year and that he would like its first projects to devise measures to tackle climate change and develop the EU's energy policy.

Clusters are an important feature of the policy, since there is evidence that economic performance of companies in close proximity is closely linked to innovative activity. The Commission is developing a map of clusters in Europe containing employment details and data on how they have evolved over time to give policy makers a clearer picture of the dynamics of industrial change.

It is looking to establish a European Cluster Alliance this year to encourage closer practical cooperation between regional governments, and will develop the theme of transnational collaboration at a conference in Stockholm next January.

The Commission will present ideas later this year on the initiatives that can be taken to develop lead markets – emerging areas with promising economic and societal value. It has chosen six where public authorities could help them develop, through their use of policies such as public procurement and standards.

Until now, innovation has been largely associated with manufacturing industry. The Commission is now turning its attention to services and is planning to launch a European incubator platform for innovative start-ups in service sectors.

Other initiatives in the pipeline include streamlining the European standardisation system so that it can respond more efficiently to industry developments, launching of joint technology initiatives (JTIs) under the 7th research and technological development framework programme and promotion of crossborder investment by venture capital funds.

The Commission has already ticked off one of the items on the list by producing a guide earlier this year on how public procurement can be used to stimulate innovation.

Two specific innovation support initiatives – Europe INNOVA and PRO INNO Europe – will help to implement some of these strategic priorities. Under the first, public/private partnerships will be established to address issues such as greening industry and eco-innovation, cluster policy, services and innovation, lead markets and high growth SMEs, known as gazelles.

The second will help in the development of the European Cluster Alliance, devising an effective intellectual property rights framework and encouraging innovation in services. In addition, the Commission is working closely with national innovation agencies during this implementation period.

CESAR SANTOS GIL

entr-innovation-policy-development@ec.europa.eu

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ec.europa.eu/enterprise/library/ee_online/art29_en.htm



Animal testing: Europe goes alternative

Developing alternative methods that can reduce the use of animal testing is a moral obligation. Under certain pieces of European legislation, it is also a regulatory requirement. In November 2005 – following European Parliament and industry discussions to ban animal testing for cosmetic products – the European Commission, seven industry sectors and individual companies joined forces to create the European Partnership for Alternative Approaches to Animal Testing (EPAA). In a unique collaborative effort, the partners work together on the '3Rs', finding ways to replace, reduce and refine existing animal tests by using the best of science and modern alternative approaches.



The search for alternatives to animal testing is not new. But the creation of the European Partnership for Alternative Approaches to Animal Testing by the European Commission has given the exercise higher visibility, extra urgency and a new dimension.

For the first time, seven major manufacturing sectors – soaps and detergents, chemicals, cosmetics, pharmaceuticals, bio-industries, crop protection and animal health – have joined forces to develop mutual trust and share their experience in devising new approaches to safety testing based on the 3Rs.

The EPAA provides a forum where the regulators (represented by the European Commission) and the regulated (industry) can meet. The Partnership focuses on the challenges – promoting the development of alternative tests and approaches and examining the validation process and methods to ensure these approaches can be accepted by regulators as proof that a product is safe for humans and the environment.

The initiative is not only designed to replace animal testing with other approaches. EPAA members are also committed to finding ways to refine and reduce the use of animals in those tests. Significant benefits arise, for example, through the exchange of information on experiments that have already been completed, thereby avoiding redundancy.

Interest groups are not members of the Partnership, but they can participate in its relevant working groups. In addition, the Partnership has created a mirror group of individuals who are invited for their specific expertise. Chaired by German Socialist MEP, Dagmar Roth-Behrendt, who has been heavily involved in seeking alternatives to animal testing for many years, it acts as a channel for independent assessment and advice. In her view, the EPAA is a clear demonstration of the lead the European institutions have taken in reducing animal testing. She said: "Reducing animal testing is now high on the political agenda, and feedback from the mirror group indicates that the EPAA has strong support from academics, experts and NGOs".

Participating European industry associations

- The Association for Soaps, Detergents and Maintenance Products (AISE)
- The European Chemical Industry Council (Cefic)
- The European Cosmetic Toiletry and Perfumery Association (Colipa)
- European Crop Protection Association (ECPA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- European Association for Bioindustries (EuropaBio)
- International Federation for Animal Health Europe (IFAH-Europe)

Five working groups

The EPAA's work is guided by its action programme, adopted in May 2006, which sets out its initial short,



The European Partnership for Alternative Approaches to Animal Testing

medium and long-term activities. This contains five main themes that are being implemented by a similar number of working groups involving over 100 experts.

The first working group is drawing up an inventory of all the alternative tests carried out by industry and of current EU, national and industry research on alternative approaches. Collecting data on inhouse research in particular is notoriously difficult to achieve and the Partnership is the only forum attempting to gain a comprehensive overview of the state of play.

The second working group is identifying future research priorities based on the 3Rs strategy. For instance, reproductive toxicity testing is resource-intensive in terms of animal numbers, costs and time. The working group is therefore examining whether the existing one-generation study developed under the Agricultural Chemical Safety Assessment can be modified. This would deliver animal welfare benefits with regard to both refinement and a reduction in the number of animals used (more than 40% compared to the two-generation study).

A third group is examining how to identify, disseminate and implement best practice in the 3Rs. It will provide the Partnership's website with a new comprehensive database of all the organisations involved. Its initial mapping has identified around 50. However, activities in this area tend to be fragmented and largely addressed at the scientific community.

A regulatory review – the first of its kind – is the fourth subject under investigation in order to better understand the requirements and implementation mechanisms for tests involving animals and 3R methods.

In a first stage, the working group is concentrating on pharmaceuticals, chemicals, cosmetics and crop protection sectors.

The fifth group is examining the whole process of validation and legal acceptance by the appropriate authorities of alternative tests. It notes that these concepts are not currently implemented in a uniform manner at national, European or international level. One ongoing action is the industry's support of the work of the European Centre for the Validation of Alternative Methods.

Having clear rules and procedures is critically important, since there is little incentive to develop alternative tests and have these scientifically validated if they are then rejected by regulators, for whatever reason.

The Commission and industry agree that the current process would work more smoothly if regulators were closely involved at both stages. Their presence would help to ensure that validated tests meet regulatory needs. "We must make sure they participate in the validation process. That is the only way to have acceptance enhanced," says one industry representative.

Test case

While fully accepting the need for regulatory acceptance, the Commission would like to shorten as much as possible the delay between scientific validation of a new alternative test and its acceptance by regulators to enable it to be used by industry.

To achieve this, Günter Verheugen, the Enterprise and Industry Commissioner, proposed to the EPAA at its first annual conference last December that it takes as a test case the new alternative method developed for pyrogenicity, to establish if there is a risk of fever-causing agents. "This analysis can then be presented at the next conference so that we can reflect how to improve and accelerate the process," he explained.

While it is impossible to state with any accuracy the number of animals currently used in all laboratory tests, or the number that could be replaced, the Commission's answer to one specific test, gives an indication of the scale of the benefits that could be achieved.

Animal numbers for pyrogen testing in Europe are estimated at about 200,000 per year. The new methods provide for a replacement of the rabbit test and the Commission expects that a high number of animals can be saved through the progressive adoption of the non-animal tests for pyrogenicity.

EPAA – in particular its second working group – is identifying research priorities, especially in the fields of health and environment. It will communicate these to the Commission's Directorate-General for Research in the hope that they will be taken into consideration for future calls.

Research

The European RTD Framework Programmes have long supported research work to replace, refine and reduce the use of animals in the safety testing of chemicals. Within the Sixth Framework Programme (FP6), some €90 million was invested in 'Health' and 'Environment and Sustainable Development' programmes on this topic. The last Integrated Project selected for funding under FP6 – involving 32 partners and €10 million in financial support – will start in April 2007. It will develop intelligent strategies to make better use of existing test and non-test information.

Under the recently launched Seventh Framework Programme (FP7), which runs from 2007 to 2013, there is a call for research proposals in the areas of health and environment. Actions will include developing a research strategy with the ambitious goal of totally replacing animal testing in the field of repeat dose systemic toxicity. This is expected to take a decade or longer to achieve.

Future

The Partnership has agreed a work plan for at least five years. Now that the preparatory work of 2006 has been completed, all members are aware that external stakeholders are expecting to see concrete results soon.

The Commission, too, will use its extensive international contacts to ensure that major stakeholders, such as the OECD, and trading partners, such as the US, are aware of developments so that alternative methods will be internationally accepted.

CORNELIS BREKELMANS

entr-consumer-goods@ec.europa.eu

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Simpler access to information for SMEs

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The European Commission recently launched its new European portal for SMEs. This will make it easier for Europe's over 23 million small and medium-sized enterprises (SMEs) to find online information on EU activity. The portal provides SMEs with a single access point to all relevant initiatives. Previously dispersed according to policy area, information can now be found under themes relevant to business, such as access to finance, single market rules and ways to reach new markets. Available in 19 languages, the portal will enable SMEs to navigate the site in their mother tongue.

Commission Vice-President and Enterprise and Industry Commissioner, Günter Verheugen said: "SMEs will now know where to look for answers to their questions – at a glance and in their own language."

As well as explaining the Commission's policy for SMEs and entrepreneurship, the portal makes it easier for enterprises to find face-to-face support services and online help. A dedicated tool on funding opportunities has also been integrated to help individual SMEs identify which EU programmes are most relevant to their situation.

The portal can be accessed on: http://ec.europa.eu/enterprise/sme/



