

# EVALUATION OF THE APPLICATION OF THE THINK SMALL FIRST PRINCIPLE IN EU LEGISLATION AND PROGRAMMES

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## EXECUTIVE SUMMARY

### This evaluation

GHK and Technopolis were commissioned by DG Enterprise and Industry of the European Commission to undertake an evaluation of the application of the Think Small First principle in EU legislation and programmes. The focus of the study was on the application of SME specific measures within EU legislation and programmes, in line with the principles of Think Small First.

The study involved a 'screening' of all 13,200 Council and Commission Directives and Regulations that are currently in force, and all EU programmes that are relevant to businesses, in order to identify where SME specific measures have been used. Following this, a detailed review was undertaken of the text of each piece of legislation that contained an SME specific measure, and the supporting documentation for each EU programme, the purpose of which was to 'map' which measures had been used, and why. Alongside this desk-based work, the views of national experts and business associations were collected through a workshop and an email consultation exercise.

### Evaluation results

#### *The use of SME specific measures in EU legislation*

On the basis of the screening of all Council and Commission Directives and Regulations currently in force, 83 pieces of legislation were found to contain SME specific measures<sup>1</sup>. Of these 83 pieces of legislation, 44 (53 per cent) only contained a reference to SMEs (i.e. that the legislation *only* contained a statement to the effect that the needs of small businesses should be taken into account, but did not specify how this should be done). 39 pieces of legislation (47%) contained an SME specific measure, of which:

- § 19 included a *size-related exemption*, whereby SMEs were exempted from certain requirements of the legislation (e.g. Directive 72/221 – annual surveys of industrial activity – where businesses employing fewer than 20 people were only surveyed once every five years);
- § 11 included *special treatment for SMEs*, the most common of which was reduced fees (e.g. Regulation 2049/2005 which set the fees charged by the European Medicines Agency and stipulated that fees for SMEs would be reduced by 90 per cent);
- § 5 included a *temporal exemption*, whereby SMEs were exempt from the requirements of legislation for a set period of time (e.g. Directive 2002/14 – a general framework for consulting employees – which allowed a transitional period of an extra two years for firms employing up to 150 people);
- § 5 *simplified or coordinated national legislative requirements* with the specific aim of benefiting SMEs (as opposed to improving the general business

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<sup>1</sup> Note that this does not correspond to the total number of cases where Think Small First has been applied, since this also includes the non-legislative consideration of the needs of SMEs (through consultation), and also the resolution of problems facing SMEs through legislative harmonisation and simplification (e.g. through the internal market)

environment). Directive 2006/123 – the Services Directive – created a single contact point in all businesses to provide information and support to businesses which was considered particularly helpful for SMEs;

- § 4 included *tailor-made information and guidance*, whereby systems were created (such as a helpdesk) in order to provide assistance to SMEs in respect of the requirements of the legislation (e.g. Regulation 1907/2006 – REACH – which included a system of national helpdesks).

Five pieces of legislation were found to contain combinations of the SME specific measures outlined above (e.g. Regulation 761/2001 – participation in the EMAS environmental scheme – which exempted SMEs from certain reporting requirements and also included the provision of technical assistance for SMEs).

The use of SME specific measures within EU legislation was discussed at a workshop held on 29 May that was attended by representatives from the Member States. According to workshop attendees, the most useful SME specific measure was the simplification and coordination of national legislation, which is a common result of some EU legislation, but is rarely implemented explicitly for the benefit of SMEs. Tailor-made information and guidance was rated as the next most useful measure, followed by the use of size-related exemptions. Size-related exemptions, though the most frequently used SME specific measure in EU legislation, were considered to be potentially unhelpful, and indeed UEAPME has emphasised that there is a danger that the exclusion of SMEs from the scope of part or all of a piece of legislation may lead to the impression that they are non-compliant<sup>2</sup>.

Workshop attendees also reviewed the use of SME specific measures within different policy areas. The most relevant policy area, it was felt, was company law and taxation, through in fact this area contained only a few examples of the actual application of SME specific measures in EU legislation (just 6 cases out of the 83 reviewed). Following this, experts rated statistics and the internal market as the next most suitable policy areas for the inclusion of SME specific measures. The least suitable policy areas were deemed to be employment conditions, consumer and health protection, and occupational health and safety, since there would be a risk that the overall aim of the legislation would be compromised if any businesses were excluded or given preferential treatment.

Finally, legislation was analysed in order to ascertain the rationale for the inclusion of SME specific measures. In most cases there was little or no explanation in the text of the legislation as to why it was necessary to introduce a modification to take account of the needs of SMEs. On occasions legislation highlighted a need to reduce the scale of the administrative burden imposed on SMEs (e.g. through a fee reduction). A number of pieces of legislation regulating the pharmaceuticals industry sought to increase SME involvement in research (e.g. Regulations 1901/2006 – medicines for paediatric use; 141/2000 – orphan medicinal products; 2049/2005 – fees payable to the European Medicines Agency; and 1394/2007 – advanced therapy medicinal products), whilst in other cases SME specific measures were introduced in order to increase SME involvement in a scheme or initiative (e.g. Regulation 761/2001 – the Community eco-management and audit scheme).

### *Member States' approaches to the application of Think Small First*

How the SME specific measures included in the legislation actually operated in practice often depends on how they were transposed and implemented by the Member States. Many pieces of legislation allowed Member States considerable flexibility in how SME specific measures were defined and how they were applied. Case studies of the application of four pieces of legislation in the Member States highlighted the differences in national approaches.

Directive 2006/112 (VAT) allowed Member States to introduce exemptions for SMEs, an option that was frequently taken up. In Germany and Denmark, SMEs are allowed to report on a less frequent basis in order to reduce administration costs. In the case of Directive 96/34 (framework agreement on parental leave), however, respondent Member States had chosen not to exercise the option to introduce the SME specific measures included in the legislation (the option to allow SMEs special arrangements). For Directive 2002/14 (informing and consulting employees), Member States had utilised different size thresholds for SME exemptions. For example, whilst the Directive indicated that undertakings employing under 50 people could be exempted, in Denmark the threshold was set at 35 employees, ensuring that more SMEs would be required to comply with the requirements of the legislation.

### *EU legislation without SME specific measures*

A total of 48 pieces of EU legislation that presently do not contain SME specific measures, but arguably could do, were identified during the screening exercise (which included consultation with business groups) and reviewed in line with the application of Think Small First. Of these 48 pieces of legislation, eight were considered to affect large numbers of SMEs and also to impose considerable compliance and administrative costs on SMEs. For each of these pieces of legislation, the suitability of each of the SME specific measures was considered, in line with the toolkit for the application of Think Small First presented in Section 5 of the report. The key conclusions from this illustrative exercise were that:

- § Tailor-made information and guidance is a versatile SME specific measure that can be applied across legislative areas with the potential to ease the burden imposed by legislation, particularly where it is complex and affects a large number of firms;
- § Special treatment is a very flexible SME specific measure that can be tailored according to the legislation. Reporting requirements (where SMEs are granted the right to submit a simplified report) are particularly suitable for the application of special treatment, since this will be unlikely to affect the overall objective of the legislation yet can impose a disproportionate burden on SMEs;
- § Size-related and temporal exemptions, though effective in some circumstances, must be implemented with care since they can compromise the overall objective of the legislation by excluding businesses. In some areas the compromise would be unacceptable since a two-tier system would be created and the principle in question would be undermined. Exemptions may be suitable where SMEs make up a relatively small part of the 'problem' that legislation seeks to address.

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<sup>2</sup> UEAPME (2008) Small enterprises must not become second class enterprises: Considerations on

### *The use of SME specific measures in EU programmes*

EU programmes often recognise the specific needs of SMEs in terms of access to funding, but of the five programmes reviewed<sup>3</sup>, only two made use of SME specific measures (the Seventh Framework Programme – FP7 – and the ECO-Innovation Programme within the Competitiveness and Innovation Programme). FP7 includes the widest range of SME specific measures. At the outset, SME needs were collected through a ‘sounding board of smaller actors’, whilst actual measures include: participation targets and monitoring (15 per cent of funding to go to SMEs under the ‘cooperation sub-programme’); higher funding rates for SMEs (up to 75 per cent of eligible costs instead of 50 per cent); national contact points to provide assistance for SMEs; and a dedicated SME FP7 web service. The ECO-Innovation Programme prioritises funding bids submitted by SMEs.

### **Conclusions**

The conclusions of the evaluation have been organised around the evaluation questions set out in the Terms of Reference for the study:

- § *How effective have the SME specific measures been in making legislation more SME friendly, and are there any barriers, means or actors that affect the effectiveness of the measures?* The application of SME specific measures is one aspect of Think Small First, alongside ensuring that the legislation does not place a disproportionate compliance or administrative burden on SMEs in the first place. The expert workshop stressed that **harmonising and simplifying national law is one of the most important ways in which legislation can be made more SME friendly**, without need to include SME specific measures.

Where SME specific measures have been included in legislation, it has been difficult to assess their effectiveness without data on the size of the burdens faced by SMEs and the impact of their – presumed – reduction. The effectiveness of the SME specific measures is affected by the extent to which responsibility for their implementation has been devolved to the Member States. Many pieces of legislation allowed national legislators to define key thresholds and even to decide whether to make use of the SME specific measure. Thus **effectiveness is largely dependent on whether national authorities consider it appropriate to distinguish between SMEs and other businesses** (and thus whether they have transposed the measures), and **how measures are enforced within the Member States**. **Effectiveness is also affected by whether SMEs have responded to the opportunities**, for instance by accessing helplines and support services.

- § *Does the EU have a coherent approach to the application of the SME specific measures, and are these measures coherent within the aims and implementation arrangements for EU legislation?* Overall there is a **lack of coherence or consistency in the use of SME specific measures within EU legislation**. An obvious example concerns the fees paid by SMEs to European agencies (e.g. to have products approved for the marketplace), where in one instance (the European Medicines Agency) there is a 90 per cent fee reduction

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exemptions of smaller enterprises from EU legislation

<sup>3</sup> These were: MEDIA, the Seventh Framework Programme, the European Social Fund, the ECO-Innovation programme within the Competitiveness and Innovation Programme, and Leonardo da Vinci.

for SMEs, whilst in most others no reduction is applied. The use of SME specific measures dates back as far as 1972 and spans policy areas (and Directorates-General), and so it is perhaps inevitable that there is a lack of consistency. However, in part this lack of consistency doubtless results from the fact that there is **no systematic approach to application of SME specific measures**, particularly in terms of **defining thresholds** (e.g. size of business, extent of fee reduction, duration of temporal exclusion). Coherence could also be improved through a greater emphasis on the clarity of the **rationale for the inclusion of SME specific measures**, since a statement as to why measures have been included, together with a monitoring plan, would make clear the logic behind the application of Think Small First.

- § *What aspects of the SME specific measures are the most efficient or inefficient?*  
At present there is **insufficient monitoring and evaluation information available on the implementation and results** of the SME specific measures to enable an assessment of relative efficiency. Certain SME specific measures – e.g. helpdesks – would impose costs on national authorities, but without more detailed information on the costs saved relative to this investment it is impossible to assess efficiency.

### **Recommendations: A Think Small First toolkit**

It was decided that the most useful way in which to present the recommendations of the evaluation would be in the form of a **toolkit** for the application of the principles of Think Small First, focusing on the use of the SME specific measures. As noted above, to date there has been a lack of consistency in the way in which the various SME specific measures have been applied within EU legislation and programmes that, in part, can be attributed to a lack of a clear definition as to how and where the measures can be applied.

**The Think Small First toolkit is intended for use by legislators and policy-makers within the EU and within the Member States.** It is designed to complement existing guidance material produced by the Commission, specifically in relation to the impact assessment guidelines that are currently being revised (and the use of the ‘SME test’ in order to systematically assess the effect of legislation on SMEs), and also the application of Think Small First through the new European Small Business Act.

The toolkit has been designed as a free-standing document, and is presented as Section 5 in this report. By way of an overview, the toolkit includes information on:

- § Why it is useful to Think Small First from a strategic perspective, in particular the role of SMEs as drivers of the European economy;
- § The impacts that EU legislation has on SMEs, including the benefits (harmonisation of national laws etc), and the costs (administrative costs, compliance costs and costs associated with legal uncertainty); and
- § How the impacts of EU legislation on SMEs vary depending on the industrial sector, the type of legislation (health and safety etc), and the size of businesses (micro, small and medium).

The remainder of the toolkit consists of a set of information ‘boxes’ corresponding to each of the SME specific measures in relation to their application for legislation and for programmes. For each SME specific measure, the toolkit provides an example of their

current usage, an overview of their advantages and disadvantages, and an assessment of the circumstances where they would be most appropriate. In respect of legislation, the toolkit provides information on the following SME specific measures:

- § Size-related exemptions;
- § Temporal exemptions;
- § Simplified reporting;
- § Reduced fees;
- § Tailor-made information, guidance and support; and,
- § Online services.

For programmes the toolkit provides information on the following SME specific measures:

- § SME participation targets and monitoring;
- § Two-part application forms;
- § Pre-participation assistance (helpdesks and information and guidance); and,
- § Preferential treatment (higher funding rates and priority in the award of grants).

# 1 INTRODUCTION

## 1.1 This report

This Final Report is the third and final deliverable of the study 'Evaluation of the 'Think Small First' principle in EU legislation and programmes', commissioned by DG Enterprise and Industry from Technopolis and GHK. It follows on from the Inception Report that was submitted on 22 April 2008, the Revised Progress Report that was submitted on 4 June 2008, and the Draft Final Report that was submitted on 25 July 2008.

## 1.2 The purpose, aims and objectives of the study

The Terms of Reference that were issued by DG Enterprise and Industry indicate that this evaluation of application of the Think Small First principle will contribute towards the achievement of the Community Lisbon Programme (2008-2010). Specifically, the study will help the Commission to assess the extent to which the interests of SMEs are acknowledged and protected in existing Community legislation and programmes. The purpose of this exercise is to ascertain the 'status quo' in order to assist with the development of a coherent approach to the future application of specific rules for SMEs (in line with the principle of Think Small First).

According to the Terms of Reference, the aim of the study is to:

*'Identify and evaluate the effectiveness of the specific rules for SMEs and their coherent application in accordance with the Think Small First principle'.*

It should be noted that the focus of the study, therefore, is on the use of specific rules for SMEs (henceforth SME specific measures), not on the broad application of the principles of Think Small First (i.e. activities that assist SMEs, but not necessarily explicitly, such as the Better Regulation agenda).

To meet aim of the study, the Terms of Reference identified two sets of objectives:

- § To apply methodologies for evaluating the relevance, coherence, utility, effectiveness and efficiency of the SME specific measures in EU legislation and programmes;
- § To provide recommendations regarding:
  - The most effective ways to implement the Think Small First principle in the policy areas scrutinised;
  - The sectors and legislation where SME specific measures do not exist but could usefully be introduced;
  - How to reach the right balance between subsidiarity and the need to ensure a level playing field for SMEs in the internal market;
  - How to ensure the right balance between the objective of having specific rules for SMEs and the possibly conflicting objectives of the internal market.

The methodology employed by the study team to address these objectives is outlined in Section 2.

### 1.3 Think Small First: policy background

Small and medium sized enterprises (SMEs)<sup>4</sup> form a significant part of Europe's economy: it is estimated that there are around 23 million SMEs in the EU, or 99 per cent of all enterprises<sup>5</sup>. SMEs are a significant source of employment and value added. In the non-financial services sector, for instance, in 2005 it was estimated that SMEs accounted for 68 per cent of total EU-27 employment and 63 per cent of valued added<sup>6</sup>. In certain sub-sectors such as the wholesale industry, the motor trade and the real estate industry, SMEs accounted for over 85 per cent of employment, and over 70 per cent of value added.

The European Commission recognises that SMEs are a driving force of innovation, job creation and economic prosperity. In 2005 the Commission adopted a '*modern SME policy for growth and employment*' which included a programme of measures designed to better coordinate and deliver support to SMEs<sup>7</sup>. These included a need to promote entrepreneurship, to improve SMEs' access to key markets, to strengthen dialogue with SME stakeholders, to improve SMEs' growth potential, and to reduce the regulatory burden on SMEs. The 'Think Small First' principle cut across this programme of measures and was intended to ensure that SME specific issues and concerns were mainstreamed into Community and national policies.

The application of Think Small First has been particularly evident in respect of the Commission's goals to make the regulatory environment more SME friendly. The 2005 *Modern SME policy* Communication suggested that SMEs are particularly sensitive to the effects of EU regulation since they have '*limited resources and insufficient expertise to comply with often complex rules and regulations [and] may also suffer disproportionately from administrative burdens*'. Various studies by the European Commission, the Member States and other organisations have collected evidence on the scale of this 'disproportionate' regulatory burden:

- § A 2001 survey of 8,000 SMEs in 11 countries by the OECD found that average annual administrative compliance costs per employee were equivalent to €4,640 for businesses employing between 1-19 people, €1,510 for businesses employing between 20-49 people, and €910 for businesses employing between 50-500 people<sup>8</sup>;

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<sup>4</sup> Throughout this report we have made use of the European Commission's standard definition of an SME, as set out in Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises. According to this definition, an SME is an enterprise that employs fewer than 250 people, has an annual turnover of less than €50 million, and a balance sheet of less than €43 million. There are additional definitions of micro, small and medium sized firms.

<sup>5</sup> [http://ec.europa.eu/enterprise/entrepreneurship/facts\\_figures.htm](http://ec.europa.eu/enterprise/entrepreneurship/facts_figures.htm)

<sup>6</sup> Eurostat (2008) Enterprises by size class: overview of SMEs in the EU

<sup>7</sup> COM(2005) 551 Implementing The Community Lisbon Programme : Modern SME Policy For Growth And Employment

<sup>8</sup> OECD (2001) Business Views on Red Tape: Administrative and Regulatory Burdens on Small and Medium-sized Enterprises'. Estimated at an exchange rate of €1=€1.4736 (European Central Bank).

- § An EU study found that, on average, where a large company spends €1 to comply with a regulatory duty, a medium-sized company will have to spend €4, and a small business will have to spend €10<sup>9</sup>;
- § A study carried out in the UK in 2000 reported that, on average, a business employing between 1-2 people spent 6.4 hours per month per employee dealing with government regulations, compared to 4.1 hours per employee for a business employing between 3-4 people, 1.4 hours per employee for a business employing between 20-49 people, and 1.3 hours per employee for a business employing over 50 people<sup>10</sup>.

There are a number of reasons why SMEs tend to expend relatively more resources than large companies complying with regulation. These include the fact that many administrative costs are fixed, that large companies can employ specialists who are more efficient at meeting regulatory requirements, and that it is often the entrepreneur within a small business who has to deal with the regulation, thus diverting valuable resources away from other business operations. More generally, alongside Think Small First, through its Better Regulation programme the European Commission is seeking to reduce the regulatory burden associated with EU legislation which will benefit SMEs as well as larger businesses.

Though there was never a formalised procedure set up for the application of the Think Small First principle to EU regulation, the 2005 *Modern SME policy* Communication made it clear that EU legislation would henceforth '*systematically*' take into account the needs of SMEs and the effect that the proposals would have on SMEs' growth and innovation potential. Specifically, the Communication indicated that '*both at national and EU level, appropriate measures to lighten the legislative burden on SMEs should always be considered and it may be useful to introduce specific provisions for SMEs*'. These specific measures included '*longer transition periods, reduced fees, simplified reporting requirements, even exemptions, or assistance, like helpdesks*'.

In May 2007 a panel of experts from the Member States, under the guidance of the Commission, published a report entitled '*Models to reduce the disproportionate regulatory burden on SMEs*' that explored in more detail how SME specific measures could be included within legislation, based on national experiences<sup>11</sup>. Following this, in October 2007 the Commission published a mid-term review of the *Modern SME policy* and the way in which the Think Small First principle had been applied<sup>12</sup>. Specifically in respect of the regulatory environment, the 2007 Communication indicated that the Commission regularly measures the impact of new legislation on businesses, but emphasised that the principles of Think Small First still need to be applied more systematically across relevant legislation.

Most recently, the Commission published a Communication to the October 2007 Meeting of Heads of State and Government entitled '*The European Interest:*

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<sup>9</sup> European Commission (May 2007) Models to Reduce the Disproportionate Regulatory Burden on SMEs. Report of the Expert Group

<sup>10</sup> Chittenden, F. *et al* (2002) Regulatory burdens of small business: a literature review

<sup>11</sup> European Commission (May 2007) *op cit*

<sup>12</sup> COM(2007) 592 Small and medium-sized enterprises - Key for delivering more growth and jobs: a mid-term review of Modern SME policy

*Succeeding in the age of globalisation*' which identified the establishment of a more dynamic business environment (particularly for SMEs) as one of four priority areas within the renewed Lisbon Strategy<sup>13</sup>. In addition to the Think Small First principle, the Communication outlined a proposal for a European Small Business Act which includes a range of measures designed to promote the prosperity of SMEs<sup>14</sup>. Following an extensive consultation exercise, the Small Business Act for Europe was adopted by the Commission on 25 June 2008.

#### 1.4 Structure of this report

The remainder of this report is structured as follows:

- § Section 2 summarises the methodology employed by the study team to address the evaluation aims and objectives outlined in Section 1.2 above;
- § Section 3 presents the results of the evaluation;
- § Section 4 outlines the conclusions and recommendations of the study team;
- § Section 5 presents a toolkit for the application of Think Small First to EU legislation and programmes that was developed by the study team on the basis of the results of the evaluation.

The Annexes to the report contain the bulk of the information collected by the study team regarding EU legislation and programmes:

- § Annex 1 contains the results of the review exercise carried out on the 83 pieces of EU legislation that included SME specific measures;
- § Annex 2 contains the results of the review exercise carried out on selected EU programmes that included SME specific measures;
- § Annex 3 contains the results of the review exercise carried out on 48 pieces of EU legislation that do not presently include SME specific measures;
- § Annex 4 lists the individuals consulted and the documentary evidence reviewed over the course of the study;
- § Annex 5 lists the pieces of legislation specifically mentioned by stakeholders as problematic for SMEs.

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<sup>13</sup> COM(2007) 581 The European Interest: Succeeding in the age of globalisation. Contribution of the Commission to the October Meeting of Heads of State and Government

<sup>14</sup> Including a need to design legislation according to the principle of Think Small First

## 2 RESEARCH METHODOLOGY

This section of the report presents an outline of the method of approach employed by the study team in order to address the aims and objectives of the evaluation (set out in Section 1.2). The section commences with a summary of the evaluation questions set out in the Terms of Reference for the assignment, and then presents a description of the key research tasks undertaken.

### 2.1 Evaluation tasks and questions

The study specification issued by DG Enterprise and Industry outlined a set of tasks that the evaluation was expected to carry out:

- § To perform a thorough screening of the Community *acquis* in the relevant areas in order to identify SME specific measures included within the legislation;
- § On the basis of this screening, to evaluate the effectiveness, coherence, efficiency and utility of these specific measures and to assess whether they provide adequate solutions to SMEs in light of the regulatory and administrative obligations created;
- § To select a sample of pieces of legislation offering Member States the option to introduce SME specific measures and examine their implementation at a national level;
- § To identify sectors and legislation that do not contain SME specific measures and analyse whether it would be advisable, possible and economically significant to include such measures;
- § To recommend improvements that could be made in respect of the application of SME specific measures in Community legislation.

The evaluation questions as set out in the study specification were as follows:

- § To what extent have the specific rules for SMEs contributed towards rendering the legislation more SME friendly?
- § How effective are the specific rules for SMEs as a means to achieve their stated objectives? What could be done to render the implementation of the Think Small First principle more effective as a means to achieve these objectives?
- § What are the barriers to the effective implementation of specific rules for SMEs? How could such barriers be overcome?
- § Are there any aspects, means or actors that render some of the specific rules for SMEs more or less effective than others, and if so, what lessons can be drawn?
- § To what extent does the EU have a coherent approach to specific rules for SMEs, and what should be the essence of this approach?
- § How coherent are these specific rules for SMEs within the aims and implementation arrangements for each piece of legislation?
- § What aspects of the specific rules for SMEs are the most efficient or inefficient? What does this represent in terms of administrative and reporting burdens on stakeholders?

- § To what extent could measures be taken to improve the utility of the Think Small First principle and what would these measures be? What lessons learned from the implementation of the specific rules for SMEs are useful for the further implementation of the Think Small First principle?

## 2.2 The study methodology

The methodology for the study was first outlined in the Revised Proposal submitted to DG Enterprise and Industry on 10 March 2008, and finalised following a kick-off meeting held between the Steering Committee and core members of the study team on 4 April 2008. The study was divided into an inception phase followed by four tasks:

- § Task 0 (inception phase): Screening of all EU legislation and programmes in preparation for the more detailed review;
- § Task 1: Review of relevant EU legislation and programmes;
- § Task 2: Assessment of Member State approaches to the implementation of SME specific measures;
- § Task 3: Assessment of where SME specific measures might be included within EU legislation and programmes;
- § Task 4: Address the evaluation questions and develop conclusions and recommendations.

The remainder of this section provides a review of the research activities undertaken as part of each of these study tasks.

## 2.3 Task 0: Screening of EU legislation and programmes

Work commenced with a kick-off meeting held between the Steering Committee and core members of the study team, the purpose of which was to validate the method of approach and identify the key sources of information. Following the kick-off meeting, the study team undertook an initial screening of EU legislation and programmes, the purpose of which was to systematically identify where SME specific measures had been included, and where they had not (but where there would be merit in their inclusion). The screening exercise included all Council and Community Directives and Regulations that are currently in force (roughly 13,200), and all current EU programmes that are relevant for businesses (i.e. excluding programmes targeting public sector authorities). Screening involved a number of separate activities (See Figure 2.1):

- § Interrogation of the EUR-LEX database of all 13,200 Council and Community Directives and Regulations using search terms to identify where SME specific measures were included in the text of the legislation<sup>15</sup>;
- § Consultation with representatives of the Directorates-General responsible for legislation with a potential impact on SMEs in order to identify which EU legislation and programmes did and did not include SME specific measures (see Annex 4 for a list of consultees<sup>16</sup>);

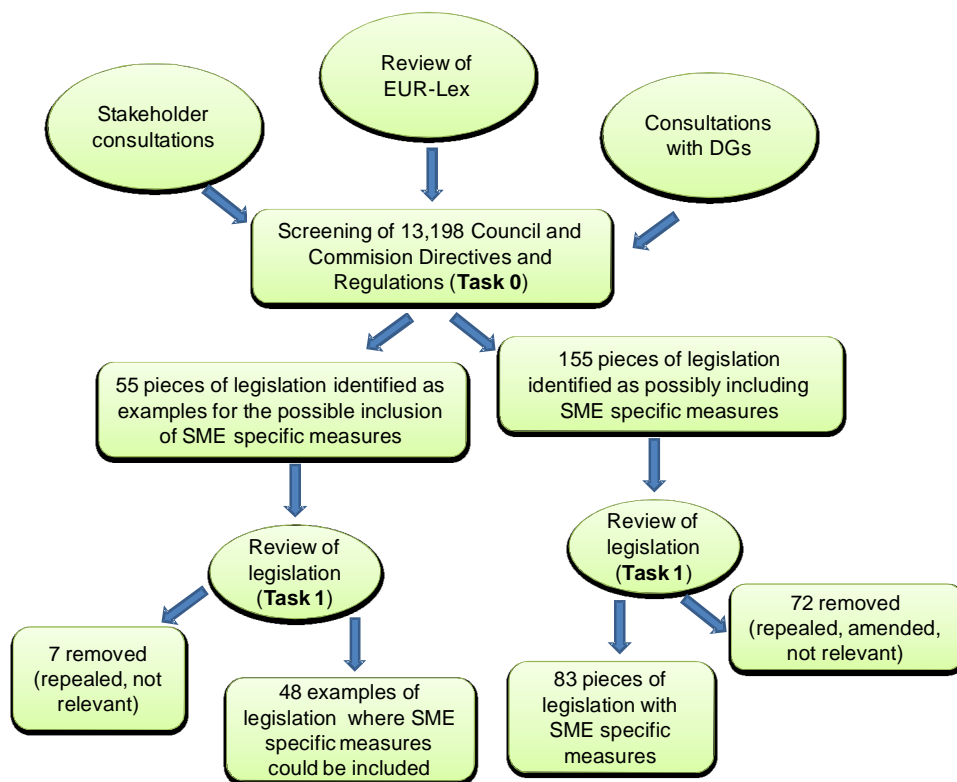
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<sup>15</sup> These were: “small and medium”; “small or medium”, “SME”, “small undertaking”, “small business”, “small enterprise”, “small retail”.

<sup>16</sup> These were from: DG Employment; DG Environment; DG Information Society and Media; DG Transport and Energy; and DG Agriculture.

§ Consultation with representatives from four European small business associations (see Annex 4 for a list of consultees)<sup>17</sup> in order to identify which EU legislation and programmes included SME specific measures, and which presently did not, but were seen to be particularly problematic for SMEs. On the whole consultees were only able to identify general legislative areas of interest (mainly relating to occupation health and safety, the environment, company law and taxation, and consumer and health protection)<sup>18</sup>.

**Figure 2.1: Method diagram illustrating the screening and review process applied to EU legislation (with and without SME specific measures)**



The results of these separate strands of activity were synthesised into three 'long lists' of legislation and programmes for more detailed review during Task 1 of the study:

- § EU legislation that includes SME specific measures (155 pieces of legislation, subsequently reduced to 83 pieces of legislation during Task 1);
- § EU legislation that presently does not include SME specific measures, but arguably could do (55 pieces of legislation, subsequently reduced to 48 pieces of legislation during Task 1). Whilst not a comprehensive list of all legislation that could be amended in line with the principles of Think Small First, this list was instead an indication of the areas that could be considered a priority, or best

<sup>17</sup> These were from: Business Europe; UEAPME; Eurochambres; and the European Small Business Alliance

<sup>18</sup> Though in some cases, business associations did identify specific pieces of legislation that were problematic for SMEs. These are listed in Annex 5.

illustrate how Think Small First could be applied. Legislation was identified on the basis of the stakeholder consultations outlined above, together with the priority legislative areas identified in the Terms of Reference for the study<sup>19</sup>;

- § EU programmes that include SME specific measures (consisting of 5 programmes):
- MEDIA;
  - The Seventh Framework Programme (FP7);
  - The European Social Fund (ESF)
  - The ECO-Innovation Programme (part of the Competitiveness and Innovation Programme);
  - Leonardo da Vinci.

Whilst these three lists were as comprehensive as could be assembled within the timescale of this study, it should be noted that this is not an exhaustive database of all legislation and programmes that involved the application of the principles of Think Small First, since:

- § The screening process focussed on the identification of legislation that explicitly targeted SMEs (i.e. through the use of SME specific measures), but the Think Small First principle also applies where legislation provides a solution to a problem that disproportionately affects SMEs. This is particularly true of the significant body of legislation relating to the harmonisation and simplification of national laws, mostly in respect of the achievement of the single market. Whilst this legislation is usually not targeted specifically at SMEs, the benefits would arguably be felt disproportionately by SMEs;
- § The Think Small First principle also includes 'softer' legislative processes such as improved consultation with SMEs and SME representatives that seeks to ensure that legislation takes account of the needs of SMEs. However, a record of this process would not be included in the text of the legislation (unless it resulted in the inclusion of an SME specific measure), and so such legislation has not been included in this study.

Upon completion of this work an Inception Report was submitted to the Steering Committee, and approved following a meeting held on 24 April 2008.

## 2.4 Task 1: Detailed review of relevant EU legislation and programmes

During Task 1 the long lists assembled during Task 0 were reviewed in order to explore the application of SME specific measures (see Figure 2.1). The review exercise consisted of analysis of the text of each piece of legislation together with the accompanying description on the Scadplus website<sup>20</sup>. Where relevant, reviews were undertaken of supporting documentation including impact assessments and Commission proposals, though the coverage and depth of this evidence was patchy. The review process involved the identification and analysis of a number of issues:

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<sup>19</sup> These were: employment and health and safety; consumer protection; environment; taxation; internal market; competition; transport; energy; research; and cohesion and rural development policies.

<sup>20</sup> <http://europa.eu/scadplus>

- § Background information including the date that legislation was adopted and the deadline for transposition;
- § The problem that the legislation was designed to address, and the aim of the legislation;
- § The effect that the legislation would have on businesses (reporting requirements, authorisation requirements etc), and whether these effects would impact disproportionately on SMEs;
- § Where legislation included SME measures, what these measures were and why they were introduced.

For programmes, the relevant legislative text was analysed alongside the programme websites and supporting documentation (e.g. guidance documents, fact sheets, participation rules). The review aimed at identifying the following issues:

- § The objectives of the programme and the actions funded;
- § The requirements to obtain funds;
- § Whether there was a focus on SMEs, and if so whether there were any specific measures designed to improve SME access to the funding.

The results of the review process for EU legislation and programmes are analysed in Section 3, and presented in tabular form in more detail in Annexes 1 to 3.

## 2.5 Task 2: Assessment of the approaches taken by Member States

The purpose of Task 2 was to explore how Member States applied the SME specific measures identified in Task 1, since many pieces of legislation gave national authorities scope to adapt these measures to meet their particular needs. A number of activities were undertaken:

- § An expert workshop was held on 29 May 2008 attended by 21 representatives from the Member States and representatives from business organisations (see Annex 4 for a list). The purpose of the workshop was to identify and discuss national approaches to the use of SME specific measures;
- § The workshop was followed by an email request sent to all attendees for further information about national approaches to the use of SME specific measures;
- § The national implementation of four pieces of EU legislation that included SME specific measures was analysed. These were agreed with the Steering Group and chosen on the basis of:
  - Whether there is scope for variations in the application of the SME specific measure as the legislation is transposed;
  - Whether legislation affects large numbers of SMEs;
  - Whether legislation is specific about the details of the SME specific measure, or whether the details are subject to decision by Member States.

An email request was sent to workshop attendees asking them to provide information on how these specific pieces of legislation had been implemented

in their respective countries. A total of five Member States provided information.

## **2.6 Task 3: Identification of legislative areas suitable for SME specific measures**

On the basis of the information assembled over the course of the evaluation, the study team developed a 'toolkit' intended for use by legislators and policy-makers at both an EU and national level. The toolkit provides an overview of the Think Small First principles, including an assessment of the rationale for the inclusion of SME specific measures within EU legislation and programmes. The toolkit also provides an overview of the operational advantages and disadvantages of each of the SME specific measures that would be of use for legislators seeking to 'design-in' ways in which to make EU legislation – and its national implementation – more SME friendly. The toolkit is presented in Section 5.

## **2.7 Task 4: Address evaluation questions and develop conclusions and recommendations**

The final task for the study was to draw together the results of the research undertaken during Tasks 0 to 3 in order to answer the evaluation questions set out in Section 2.1 above, and on the basis of this to develop the conclusions and recommendations of the study. A Draft Final Report was prepared by the study team and discussed at a Steering Committee meeting that was held on 30 August 2008. Following this, a second expert workshop was held on 25 September 2008 that was attended by members of the study team, representatives of the Steering Committee, and national experts and representatives of business associations. The results of the study and the toolkit were presented and discussed at this workshop. Comments received at the Steering Committee meeting and the expert workshop have been integrated into this Final Report.

## 3 EVALUATION RESULTS

This section of the report presents the results of the evaluation of the use of SME specific measures in EU legislation and programmes, in accordance with the application of the principles of Think Small First. The section is organised as follows:

- § An overview of the use of SME specific measures within EU legislation;
- § Analysis of Member State's approaches to the national application of Think Small First;
- § Analysis of selected pieces of EU legislation that presently do not contain SME specific measures, but that might benefit from the inclusion of such measures;
- § The application of the principles of Think Small First in selected EU programmes.

### 3.1 The use of SME specific measures in EU legislation

#### 3.1.1 Overview of legislation with SME specific measures

Following the initial screening exercise of all of the EU legislation currently in force, a total of 83 pieces of legislation were found to contain SME specific measures (though, as discussed in Section 2.3, the principles of Think Small First can be employed without the use of SME specific measures). A detailed review of the text of each of the 83 pieces of legislation was carried out in order to ascertain how and why SME specific measures had been utilised.

Table 3.1 shows the spread across policy areas of the 83 pieces of EU legislation that contained SME specific measures. Legislation governing occupational health and safety was the single largest policy area that included SME specific measures (equal to 26.5 per cent of the 83 pieces of legislation reviewed), closely followed by legislation relating to the internal market (24.1 per cent of the total). Taxation and company law were the policy areas that contained the lowest number of pieces of EU legislation containing SME specific measures. Again, this sectoral spread does not reflect the application of the principles of Think Small First more generally, only where SME specific measures have been used. This is particularly true of legislation affecting the internal market, and the data presented in Table 3.1 are likely to be an underestimation of the number of pieces of SME friendly legislation, since by definition the harmonisation of national laws reduces costs for all businesses. In almost all cases, however, this was not done *explicitly* for the benefit of SMEs.

**Table 3.1: Policy areas of the EU legislation containing SME specific measures**

Policy area	Number	% of the total
Occupational health and safety	22	26.5%
Internal market	20	24.1%
Employment conditions	10	12.0%
Environmental protection	10	12.0%
Statistics	8	9.6%

Consumer and health protection	7	8.4%
Company law	4	4.8%
Taxation	2	2.4%
<b>Total</b>	<b>83</b>	<b>100.0%</b>

Table 3.2 shows the dates that legislation including SME specific measures was introduced (adopted). The majority of this legislation was introduced recently (compared to the profile of all EU legislation). Some 55 per cent of EU legislation containing SME specific measures has been introduced since 2001, compared with 12 per cent of the total body of EU legislation. A total of 45 per cent of legislation containing SME specific measures was introduced prior to 2001, with one piece of legislation dating back to 1970 (Directive 70/156/EEC regarding the type-approval of motor vehicles and their trailers). Even prior to the application of the Think Small First principle in the 2000s, a significant proportion of EU legislation took account of the particular needs of SMEs.

**Table 3.2: Date of introduction of the EU legislation containing SME specific measures**

Year of introduction	Legislation with SME measures		All EU legislation	
	Number	% of total	Number	% of total
1951-1960	0	0.0%	10	0.1%
1961-1970	0	0.0%	492	3.7%
1971-1980	2	2.4%	2,788	21.1%
1981-1990	9	10.8%	5,037	38.2%
1991-2000	26	31.3%	3,234	24.5%
2001-present	46	55.4%	1,637	12.4%
<b>Total</b>	<b>83</b>	<b>100.0%</b>	<b>13,198</b>	<b>100.0%</b>

### 3.1.2 A typology of SME specific measures

In May 2007 the Commission published the report '*Models to reduce the disproportionate regulatory burden on SMEs*<sup>21</sup> which included a typology of the measures that could be included within legislation in order to support SMEs. Ten such models were identified<sup>22</sup>, which for the purposes of this study have been grouped into five SME specific measures:

<sup>21</sup> European Commission (2007) Models to reduce the disproportionate regulatory burden on SMEs. Report of the Expert Group

<sup>22</sup> These were: size-related exemptions; reduced obligations; simplified obligations; temporal exemptions; administrative coordination; common commencement dates; tailor-made information for SMEs; electronic services; privileged treatment; and the early evaluation of regulatory impacts on SMEs.

- § *Size-related exemptions* – SMEs are excluded from some or all of the requirements of a piece of legislation (or Member States are given the right to introduce such exemptions);
- § *Special treatment* – SMEs are granted some form of special treatment, such as reduced or deferred fees;
- § *Temporal exemptions* – SMEs are expected to meet the full requirements of a piece of legislation, but at a later date than for other sizes of business in order to give them time to adapt;
- § *Tailor-made information, guidance and support services* – included in the legislation is a requirement that a service is set up specifically to provide support to SMEs, or that tailor-made information and guidance is developed;
- § *Simplification and/ or coordination of regulatory requirements* – the principles of Think Small First are often applied through regulatory solutions that improve the legislative environment for SMEs (e.g. through the harmonisation of national laws), but that are not done specifically for SMEs. As discussed above in Section 2.3, these have been excluded from the study since the focus of the evaluation was on the use of SME specific measures. In some cases, however, the screening exercise included legislation where the simplification and/ or coordination of regulatory requirements had been carried out explicitly in order to benefit SMEs (i.e. could be treated as an SME specific measure).

This typology of SME specific measure has been used throughout this report.

### **3.1.3 Overview of the application of SME specific measures in EU legislation**

As part of the review exercise, the text of each of the 83 pieces of legislation was analysed in order to determine which – if any – of these SME specific measures was included. Table 3.4 shows the results of this exercise. In just over half of all cases (53 per cent of the 83 pieces of legislation reviewed), there were no SME specific measures included in the legislation, only a statement to the effect that the needs of small businesses were to be taken into account, and/ or that the requirements of the legislation should not impose an unreasonable burden on small businesses. For the purposes of analysis these pieces of legislation have been classified as '*only a reference to SMEs*' (see Table 3.4). In these cases it is possible that such measures were introduced when the legislation was transposed (many pieces of legislation devolved the specifics of implementation to the Member States), but assessing this systematically for all legislation was beyond the scope of this study.

A total of 39 pieces of legislation included one or more of the SME specific measures listed above (equal to 47 per cent of the 83 pieces of legislation that were reviewed). The most common type of SME specific measure was a size-related exemption (found in 19 cases, equal to 23 per cent of the legislation reviewed). Following this, 11 cases of special treatment of SMEs were identified, equal to 13 per cent of the legislation reviewed. Temporal exemptions and tailor-made information and guidance for SMEs were used much less frequently in the EU legislation reviewed.

**Table 3.4: The inclusion of SME specific measures in the 83 pieces of EU legislation reviewed, by policy area (as a % of all legislation reviewed in that policy area)**

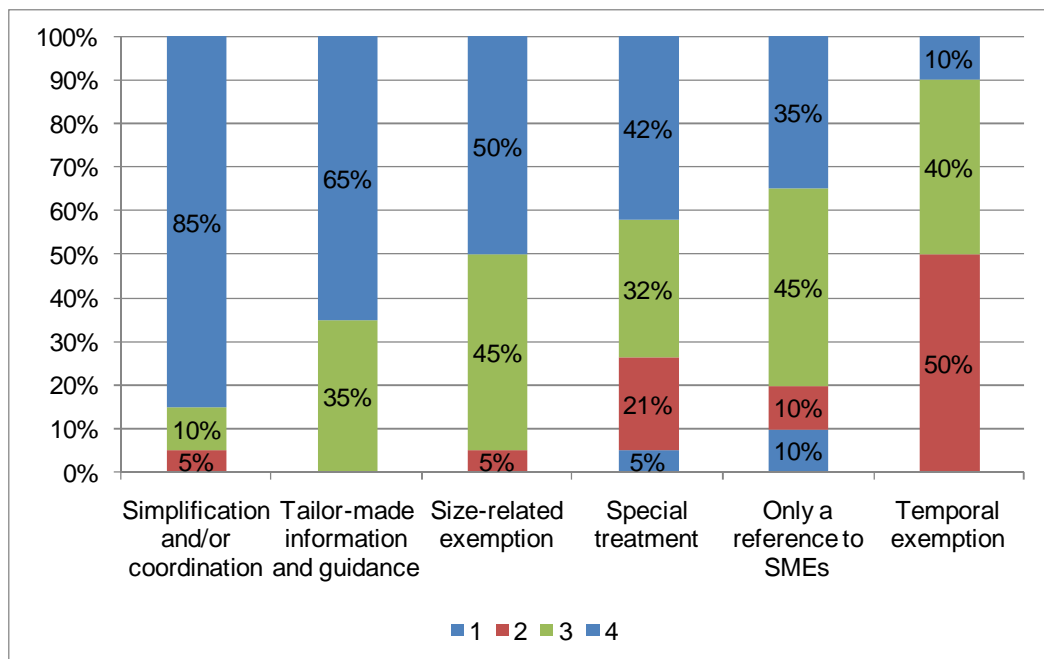
Policy area	Only a reference to SMEs		Size-related exemption		Special treatment		Temporal Exemption		Simplification and/ or coordination		Tailor-made information and guidance		Pieces of legislation reviewed <sup>#</sup>	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Occupational health and safety	19	86%	1	5%	0	0%	1	5%	0	0%	1	5%	22	100%
Internal market	8	40%	3	15%	4	20%	1	5%	4	20%	1	5%	20	100%
Employment conditions	4	40%	4	40%	1	10%	2	20%	0	0%	0	0%	10	100%
Environmental protection	4	40%	4	40%	2	20%	0	0%	0	0%	2	20%	10	100%
Statistics	4	50%	3	38%	0	0%	0	0%	1	13%	0	0%	8	100%
Consumer protection	2	29%	2	29%	2	29%	1	14%	0	0%	0	0%	7	100%
Company law	3	75%	0	0%	1	25%	0	0%	0	0%	0	0%	4	100%
Taxation	0	0%	2	100%	1	50%	0	0%	0	0%	0	0%	2	100%
<b>All</b>	<b>44</b>	<b>53%</b>	<b>19</b>	<b>23%</b>	<b>11</b>	<b>13%</b>	<b>5</b>	<b>6%</b>	<b>5</b>	<b>6%</b>	<b>4</b>	<b>5%</b>	<b>83</b>	<b>100%</b>

Note: <sup>#</sup>Legislation could contain more than one SME specific measure (there were five such cases in total), and so the sum of the number of cases of SME specific measures (i.e. columns 2-7) could exceed the total number of pieces of legislation reviewed (column 8).

During the expert workshop held on 29 May 2008, attendees were asked to rate the usefulness of each of the different types of SME specific measure in terms of reducing the scale of the disproportionate legislative burden on SMEs. For this exercise a scale of 1 to 4 was used, where 1 was equivalent to 'not at all useful', and 4 was equivalent to 'very useful'. Figure 3.1 shows the results.

Workshop attendees identified the simplification and/ or coordination of regulatory requirements as the most useful SME specific measure (rated as 'very useful' by 85 per cent of attendees), though as discussed above this is not strictly an SME specific measure. The simplification and/ or coordination of regulatory requirements is a common feature of EU legislation which seeks to harmonise national laws in order to, for example, facilitate the development of the internal market. This is rarely done explicitly for the benefit of SMEs, but instead benefits businesses more generally (though often SMEs disproportionately). After this, tailor-made information, support and guidance was rated as the next most useful SME support measure (rated 'very useful' by 65 per cent of attendees), followed by the use of size-related exemptions (rated 'very useful' by 50 per cent of attendees). Temporal exemptions and the inclusion of a reference to the needs of SMEs within the text of the legislation were rated as the least useful SME specific measures.

**Figure 3.1: Workshop attendees' rating of the usefulness of SME specific measures (scale of 1 to 4)**



Base=20 workshop attendees

The data presented in Figure 3.1 (i.e. the expert interpretation of which SME specific measures were the most useful) contrasts somewhat with the actual profile of the use of SME specific measures in EU legislation (Table 3.4). After the simplification and/ or coordination of regulatory requirements, the introduction of tailor-made information and guidance was identified by experts as the most useful SME specific measure, but was only included in a minority (5 per cent) of the 83 pieces of EU legislation reviewed. The most common SME specific measure – a size-related exemption – was rated as

'very useful' by 50 per cent of workshop attendees, but concerns were expressed by experts that the exclusion of firms could undermine the goals of legislation. Moreover, stakeholders from business organisations suggested that exempting SMEs from certain requirements might give the impression that they are non-compliant (e.g. that products produced by SMEs would be less safe as they were less regulated)<sup>23</sup>. The conclusion from the expert workshop was thus that the usefulness of SME measures varied depending on the legislation in question (see below).

### 3.1.4 *The use of SME specific measures by policy area*

There was some variation in the application of the different SME specific measures between the policy areas studied (also shown in Table 3.4). Occupational health and safety legislation was more likely to only include a reference to SMEs in the text of the legislation (86 per cent of cases), as was company law legislation (75 per cent of cases). Despite explicitly indicating the needs or impacts of SMEs should be considered, legislation in these policy areas was much less likely to *actually* include specific measures to achieve this goal. It was outside the scope of the evaluation to systematically assess whether the option to introduce SME friendly measures was taken up by national authorities.

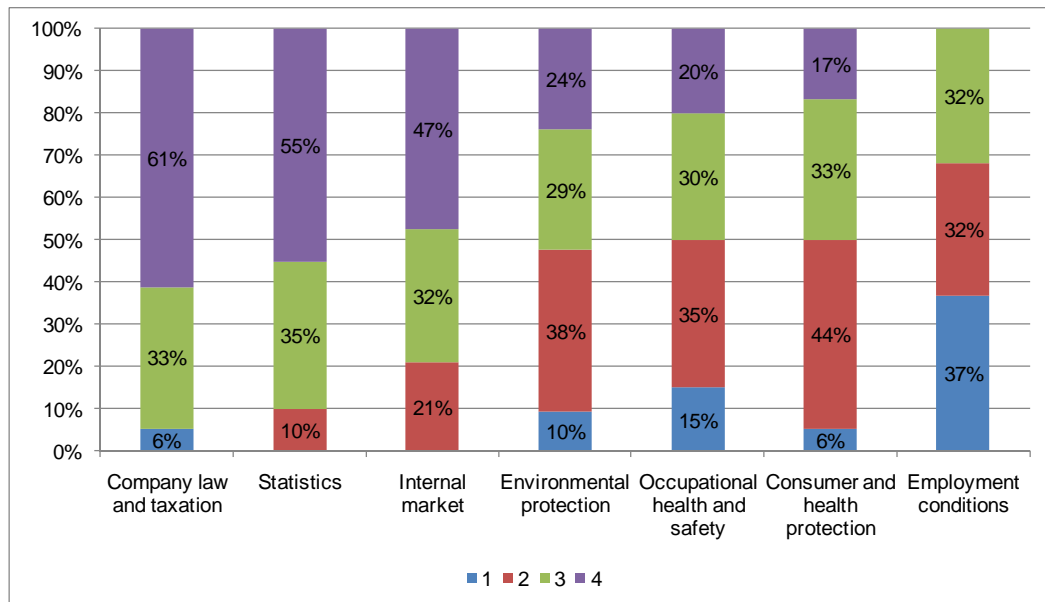
Size-related exemptions were most commonly found in legislation relating to taxation (100 per cent of cases), employment conditions and environmental protection (both 40 per cent of cases), and statistics (38 per cent of cases). Just one of the 22 pieces of EU occupational health and safety legislation reviewed included a size-related exemption. In respect of the other types of SME specific measure, the numbers of cases were too small to enable a robust statistical analysis of the results, though it is perhaps notable that legislation relating to employment conditions was more likely to make use of temporal exemptions (20 per cent of cases), and environmental legislation was more likely to make use of tailor-made information and guidance (20 per cent of cases).

During the expert workshop, attendees were asked how suitable it was for SME specific measures to be introduced into legislation in the policy areas listed above in Table 3.4. Again, for this exerciser a scale of 1 to 4 was used, where 1 was equivalent to 'not at all appropriate', and 4 was equivalent to 'very appropriate'. Figure 3.2 shows the results. Whilst experts stressed that it was difficult to provide a single answer to the question (since some SME specific measures may be suitable to one policy area but not another), the three policy areas deemed most suitable for SME specific measures were: company law and taxation (rated as 'very appropriate' by 61 per cent of workshop attendees); statistics ('very appropriate' for 55 per cent of attendees); and the internal market ('very appropriate' for 47 per cent of attendees).

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<sup>23</sup> UEAPME (2008) Small enterprises must not become second class enterprises: Considerations on exemptions of smaller enterprises from EU legislation

**Figure 3.2: Workshop attendees' rating of the appropriateness of SME specific measures to selected policy areas (scale of 1 to 4)**



Base=20 workshop attendees

Comparison with the data presented in Table 3.4 shows that, though seen as the most appropriate policy area for SME specific measures by the attendees of the expert workshop, EU company law and taxation legislation actually contained very few SME specific measures (there were just six cases, and three of these were only a reference to SMEs). Internal market legislation, on the other hand, was generally regarded by the experts as suitable for the inclusion of SME specific measures, and was also the second most common policy area that actually included such measures (there were 20 cases in the legislation reviewed).

Employment conditions, consumer and health protection, occupational health and safety and environmental protection were seen by the attendees of the workshop as the least suitable legislative areas for the inclusion of SME specific measures. Again this result does not entirely match the actual profile of the use of SME specific measures in EU legislation (Table 3.4 in Section 3.1.3). These differences can in part be explained by the fact that experts were commenting on the suitability of *all* SME specific measures within the policy areas, but it is clear that there is some divergence between how the principles of Think Small First are seen by national legislators, and how they are actually applied within the body of EU legislation.

### 3.1.5 Details of the application of the SME specific measures

There follows a review of the main observations from the review of the application of SME specific measures within EU legislation, organised on the basis of the headings outlined above in Table 3.4. More detailed information on individual pieces of legislation is included in Annex 1.

#### Size-related exemptions

Size-related exemptions were the most common type of SME specific measure found in EU legislation and are used across a variety of policy areas. 'Size' is expressed in

different ways, though is most frequently based on the number of employees. Directive 98/59 on collective redundancies, for instance, establishes consultation procedures that are only to be carried out if at least 10 dismissals are planned in companies with 20-100 employees (thus the smallest firms fall out of scope of the Directive). Medium-sized firms are only included in the case of dismissals affecting more than 10 employees. Elsewhere, exemptions from requirements in respect of the collection and reporting of statistics are also often based on the number of employees in a firm. The yearly surveys required by Directive 72/221 (annual surveys of industrial activity) are only to be carried out in enterprises employing more than 20 persons; smaller firms only have to participate every five years.

In order to define what constitutes an SME, most pieces of legislation – usually those relating to the single market – refer to the European Commission’s standardised definition for SMEs. There were, however, other definitions used within EU legislation. On occasions, size-related exemptions were defined according to trade value, turnover or production output. Directive 70/156 (type-approval of motor vehicles) allows exemptions for automotives manufactured in small quantities (defined as under 500 vehicles placed on the market annually). In other instances, there was no definition of size included in the legislation, only a reference to ‘small producers’. An example of this was Directive 2006/32 on energy efficiency, that exempted ‘small distributors or retailers of energy’ from certain reporting requirements. Overall this lack of consistency risks creating confusion as to what constitutes an SME, makes implementation and enforcement more difficult, and could create a situation where different definitions are applied across the EU (thus creating market distortions).

#### *Temporal exemptions*

In most cases temporal exemptions were not solely applicable to SMEs, but were applied in sectors where SMEs are particularly significant and legislation would thus have a disproportionate effect. Directive 2007/45, for instance, removed national legislation setting rules regarding quantities for pre-packed products, but for certain products (including milk, butter and dried pasta), the implementation of the legislation was delayed for four years in order to give ‘small retailers’ time to adapt. Similarly, Directive 2001/45 on the use of work equipment permitted a transitional period of two years to allow for SMEs in the construction sector to adapt to the requirements of the legislation. In another instance, Directive 2002/14 introduced a general framework for informing and consulting with employees, but for Member States without such statutory systems a transitional period was permitted of an extra two years for firms employing at least 150 people, and of an extra three years for firms employing at least 100 people.

Where temporal exemptions were applied there was never an explanation as to how the duration of the ‘transition’ period had been decided, nor whether there were any milestones in place in order to assess the progress that had been made by SMEs.

#### *Special treatment*

The category special treatment included a range of legislative measures targeted specifically at SMEs. The nature of the measures varied. Often SMEs were offered reduced fees, such as in Commission Regulation 2049/2005 which set the fees charged by the European Medicines Agency and stipulated that, for SMEs, fees for inspections, scientific advice and scientific services were reduced by 90 per cent. In this case the payment of fees could also be deferred until after marketing authorisation

has been granted. Fee reductions were also found in respect of Regulation 1394/2007 (advanced therapy medicinal products), Regulation 1981/2006 (the Community reference laboratory for genetically modified organisms), and Regulation 1907/2006 (REACH).

There were also a number of measures allowing for special arrangements for SMEs. The VAT Directive (2006/112) permitted Member States to implement simplified VAT charging and collection schemes for small enterprises including flat-rate VAT schemes. Another example was found in Directive 2006/48 (the taking up and pursuit of the business of credit institutions), in which smaller credit institutions were allowed to opt for a more suitable risk assessment procedure.

#### *Tailor-made information, guidance and support*

There were few examples of tailor-made information, guidance and support measures in the legislation reviewed (it is likely that such systems would often be established outside of the text of the legislation). The environmental area contains two such measures: a requirement to establish national helpdesks for the implementation of REACH (Regulation 1907/2006); and information and assistance services incorporated in the Community eco-management and audit scheme (EMAS) Regulation (761/2001). Though these measures target businesses in general and not SMEs specifically, they are likely to particularly benefit the latter.

#### *Simplification and/ or coordination of regulatory requirements*

As discussed above, this category of measures included all legislation that simplified, harmonised or coordinated regulatory or administrative requirements between Member States, with the explicit aim of benefiting SMEs. Of course, simplification and coordination benefits all businesses, but arguably SMEs benefit disproportionately<sup>24</sup>. A lack of harmonisation of national laws, or the coordination of administrative procedures between countries places additional burdens on SMEs since scarcer resources are spent collecting information on different national laws and adapting systems in order to ensure compliance.

Within the legislation reviewed, a key example of this type of SME specific measure is Directive 2006/123 (the Services Directive), which created a single contact point within each Member State in order to provide information and support to SMEs wishing to access service sector market opportunities in that country. The contact point is also able to remotely complete any necessary legal or administrative procedures (e.g. registration of professional staff). These national contact points do not exclusively provide services to SMEs, but the Directive is clear that, since SMEs make up a significant proportion of the services sectors, they will benefit disproportionately. Regulation 1901/2006 (medicinal products for paediatric use) introduces a simplified procedure for obtaining authorisation for remarketing off-patent medicine for use with children (the PUMA form). Whilst this measure will benefit all businesses, the legislation is explicit that this measure was introduced in order to simplify the procedures for SMEs.

#### *Combinations of SME specific measures*

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<sup>24</sup> Though in some cases the additional competition resulting from the opening up of markets may have a negative impact on SMEs in the short-term

The review of 83 pieces of EU legislation containing SME specific measures identified five cases where combinations of measures were included. In theory this approach has a number of advantages since the burden placed on SMEs by legislation may require more than one solution, and synergies between SME specific measures could increase their overall effectiveness. Regulation 761/2001 (participation in the EMAS scheme), for instance, included both a size-based exemption (requirements for annual reporting were removed for SMEs), and a tailor-made information and support service (including technical assistance in order to boost SME participation). Regulation 1907/2006 (REACH) made use of both tailor-made information and guidance (a system of national helpdesks), and also special treatment for SMEs (reduced fees when registering substances with the European Chemicals Agency).

### **3.1.6 *The rationale for the inclusion of SME specific measures in EU legislation***

For each of the 83 pieces of legislation reviewed, the text of the legislation was analysed in order to determine why the SME specific measure was included, and whether there was any indication of the intended outcome and/ or impact. By far the most frequent rationale cited was the need to reduce the administrative burden for SMEs, or to reduce the costs of compliance. In some cases this rationale corresponded directly to an SME specific measure (e.g. reduced fees in order to directly reduce the costs of compliance, size-based exclusion from reporting requirements in order to reduce administration costs).

Another reason for the inclusion of SME specific measures cited in the legislation reviewed was the economic importance of SMEs. Directive 2006/123 (the internal market for services) justified the inclusion of an SME specific measure on the grounds that SMEs make up such an important part of the services industry, and thus the creation of an internal market in services would generate significant numbers of jobs.

A number of pieces of legislation – largely in the pharmaceutical industry – sought to increase SME involvement in research and innovation through the introduction of support measures (termed ‘incentives’). Regulations 1901/2006 (medicines for paediatric use), 141/2000 (orphan medicinal products), 2049/2005 (fees payable to the European Medicines Agency), and 1394/2007 (advanced therapy medicinal products) all included support measures for this reason.

In a number of cases SME-friendly legislative measures were introduced in order to increase SME participation in a scheme or initiative, such as Regulation 761/2001 (the Community eco-management and audit scheme – EMAS), Regulation 2157/2001 (the Statute for a European Company), Directive 2005/32 (eco-design requirements for energy-using products), and Directive 90/496 (nutrition labelling for foodstuffs). The two public procurement Directives (Directives 2004/17 and 2004/18) both included SME specific measures with the aim of increasing SME participation in the public procurement market. A similar goal was indicated in Regulation 1370/2007 (procurement of public passenger transport services).

## **3.2 Member States’ approaches to the application of Think Small First**

The review carried out of EU legislation provides a ‘map’ of the use of SME specific measures at an EU level, as envisaged by the legislators responsible for drafting each of the Directives and Regulations. How SME specific measures actually operate ‘on the ground’ depends on how legislation was transposed and whether there are any

national approaches to thinking small first. This has been investigated through a series of case studies, the results of which are presented below.

### 3.2.1 *Implementation of selected EU legislation*

The study team undertook a review of the implementation of four case study pieces of EU legislation, each of which gave Member States the option of introducing SME specific measures. The methodology for selecting these four case studies was described in Section 2.5. The four pieces of legislation and the provisions they contain are presented in Table 3.5.

**Table 3.5: EU legislation subject to case studies**

Legislation	SME provision in EU legislation
Directive 2006/112 (the VAT Directive)	Member States are allowed to make use of exemptions and introduce flat-rate schemes for SMEs (special treatment).
Regulation 761/2001 (participation by organisations in the Community eco-management and audit scheme EMAS)	Member States must facilitate access to the scheme for SMEs, and are allowed to introduce simplified reporting.
Directive 2002/14 (informing and consulting employees)	Member States may make use of size related exemptions and temporal exemptions.
Directive 96/34 (framework agreement on parental leave)	Member States may make use of special treatment for small undertakings.

#### *Directive 2006/112 (the VAT Directive)*

The VAT Directive provides for Member States to introduce exemptions from VAT and introduce flat-rate schemes for SMEs. This possibility has been used in all the reviewed Member States. Most commonly taxable persons under a certain threshold are exempt from paying VAT. The thresholds are expressed in annual turnover or income. In two instances (Germany and Denmark) small enterprises may report on less frequent basis, such as bi-annually, quarterly or annually, as opposed to monthly, which is the case for large companies.

#### *Regulation 761/2001 (participation by organisations in EMAS)*

The Regulation stipulates that Member States must facilitate access to the Eco-Management and Audit Scheme (EMAS) for SMEs, and that they are allowed to introduce simplified reporting for these companies. The latter possibility is taken up by Austria, Germany, Latvia and to some extent Denmark that allow SMEs to update their environmental statements less frequently. In Hungary funding is provided to SMEs for making necessary changes to obtain EMAS certificates and there are dedicated information websites and brochures on the scheme. In Austria several programmes have been implemented at national level to increase awareness of EMAS and promote it and to facilitate the exchange of experience between public authorities and relevant stakeholders.

#### *Directive 2002/14 (Informing and consulting employees)*

In most of the reviewed countries, national law already regulates the participation of employees beyond the requirements of the directive; therefore no specific changes were introduced when this was transposed. Article 3 of the Directive stipulates that Member States can exempt *undertakings* with under 50 employees from the procedures laid down in the directive. The Danish authorities, however, lowered the exemption threshold to undertakings with under 35 employees, thus ensuring that greater numbers of SMEs are required to comply with the Directive than was envisaged by the EU. Directive 2002/14 also specifies that *establishments* employing less than 20 people can be exempted from the requirements of the legislation, whilst in Germany the threshold was set at five employees, again increasing the number of SMEs that were required to comply with the Directive beyond the level envisaged by the EU. In Hungary the option to exempt SMEs from the requirements of the Directive was not transposed into national law.

*Directive 96/34 (Framework agreement on parental leave)*

The provision in the EU legislation allows for Member States to authorise special arrangements for small undertakings, however there were few examples of this in the reviewed Member States. In Hungary the labour contract may fix an additional leave in case of small- and medium sized-enterprises. In Austria the right to part-time employment until the child reaches the age of seven was introduced in 2006 in companies with 20 employees or more. This Directive is another example where a possibility introduced in a piece of EU legislation is not picked up on national level.

### **3.2.2 Examples of national approaches to Think Small First**

Looking beyond EU legislation and the SME specific measures it allows for, it was also investigated whether Member States make use of the other aspects to Think Small First (at an EU level these include consultations, impact assessments etc). These can be grouped into three main types: *ex-ante approaches* (measures undertaken before legislation is adopted), *ex-post approaches* (measures carried out after legislation is adopted), and various *other measures*. Examples of measures within these groups are listed below:

§ Ex ante approaches:

- Impact assessments with specific measurements on effects on businesses and SMEs (e.g. Hungary, Austria, Latvia, Luxemburg, Finland);
- Consultation procedures with SME representative organizations (e.g. Hungary, Latvia, Slovenia, Poland);
- Veto right for Ministry of Public Affairs over legislation judged detrimental to businesses (e.g. Slovenia).

§ Ex-post approaches:

- Systematic measurement of administrative costs created by passed legislation (e.g. Hungary, Latvia);
- Regular surveys to assess measures for improvement of business environment (e.g. Latvia);
- Evaluation of legislative effects after five years in force (e.g. Slovenia).

§ Other approaches:

- Act on SMEs stipulating that the minister in charge of economic policies shall coordinate the state responsibilities related to SMEs, such as evaluate the effectiveness of state assistance and draw up a strategy for SME development policy (e.g. Hungary);
- Specific initiatives to diminish administrative burden (e.g. Hungary, Austria);
- Information and counselling services, stimulation of R&D and innovation activities, promotion of the transfer of business and funds allocated from the state budget for national financial programs for SMEs (e.g. Romania);
- Annual action plan to improve business environment (e.g. Latvia).

### 3.3 EU legislation without SME specific measures

A list of 48 pieces of EU legislation that do not presently contain SME specific measures, but where there would arguably be merit in the inclusion of such measures was identified in the screening process and including the legislative review (see Annex 3). This should not be seen as an exhaustive list of priority legislation for change, only an indication of how and why SME specific measures could be employed in EU legislation. By way of an overview, Table 3.6 shows the spread of this legislation across key policy areas. The single largest category of legislation (31 per cent of the total) concerned environmental protection, frequently identified during the consultations with SME stakeholders as a problem area.

**Table 3.6: Policy areas of the 48 pieces of legislation included in the review process where SME specific measures could be applied**

Policy area	Number of pieces of legislation	% of the total
Environmental protection	15	31%
Consumer and health protection	10	21%
Internal market	9	19%
Taxation	6	13%
Occupational health and safety	4	8%
Employment conditions	2	4%
Company law	1	2%
Statistics	1	2%
<b>Total</b>	<b>48</b>	<b>100%</b>

The review exercise for these 48 pieces of legislation consisted of an analysis of the text of the legislation including its aims, the problem addressed, and the nature and scale of the effect on businesses. On the basis of this review, an assessment was made regarding the relevance to SMEs (i.e. whether legislation affects a significant number of businesses), and the scale of the effect on SMEs (i.e. the scale of administrative and compliance costs). Results have been presented in terms of 'high', 'medium' or 'low' (see Annex 3 for details of the individual pieces of legislation).

The following pieces of legislation received a 'high' rating both in terms of relevance to SMEs and the scale of administrative and compliance costs and there would therefore be a case for considering introducing some type of SME measure:

- § *Directive 91/533* regarding an employer's obligation to inform employees of the conditions applicable to the contract or employment relationship, which obligates employers to provide significant amounts of information regarding employment conditions, not all of which may be easy for an SME to collect;
- § *Directive 2005/60* on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing, which requires credit and financial firms to collect detailed information on each financial transaction;
- § *Directive 2002/73* on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions, which requires employers to provide employees with details of their gender equality policy;
- § *Directive 95/46* on the protection of individuals with regard to the processing of personal data and on the free movement of such data, which, amongst other requirements, obliges businesses to notify authorities regarding the processing of personal data;
- § *Directive 2002/92* on insurance mediation which includes a detailed set of notification and registration requirements;
- § *Directive 2006/12* on waste and recycling, which sets out detailed requirements for the handling and disposal of waste;
- § *Directive 2003/108* on waste electrical and electronic equipment (WEEE) which makes producers responsible for the treatment, recovery and recycling of electrical and electronic waste;
- § *Directive 1999/31* on the landfill of waste, which sets detailed standards for the use of landfill, the cost of which is often passed on to small businesses.

The decision about whether to include an SME specific measure within these pieces of legislation can only be made on the basis of a thorough evaluation and impact assessment of the current and future costs and benefits to businesses (and SMEs in particular). On closer inspection, it may become clear that these pieces of legislation are not suitable for the inclusion of SME specific measures (since they may fundamentally compromise the purpose of the legislation, or it may in fact be the case that SMEs are not unduly affected by the legislative burdens, or have adapted accordingly).

However, purely as a theoretical exercise to illustrate how the decision as to whether to include SME specific measures within a piece of legislation might be informed, Table 3.7 summarises the suitability of each of the measures for each piece of legislation in turn. Each assessment makes use of a 'high', 'medium' or 'low' scoring system, depending on whether the SME specific measure is practical, how it affects the integrity of the legislation, whether it would have a significant impact, whether it is needed, and what the cost would be (versus the overall efficiency gain).

These assessments are intended to be illustrative of the process of applying SME specific measures and do not take account of the particularities of the legislation as it was being drafted. The process underpinning the decision making – together with the

strengths and weaknesses of each of the SME specific measures – is explored further as part of the toolkit for the use of Think Small First that is presented in Section 5.

A number of conclusions can be drawn from the assessments presented in Table 3.7:

- § Tailor-made information and guidance is a versatile SME specific measure that can be applied across legislative areas and has the potential to ease the burden imposed by legislation, particularly where it is complex and affects a large number of firms. As demonstrated by the example of Directive 2006/12 (waste and recycling), such a service also provides an opportunity to promote positive behaviour (e.g. increased recycling);
- § Special treatment is a very flexible SME specific measure that can be tailored according to the legislation. Reporting requirements (where SMEs are granted the right to submit a simplified report) are particularly suitable for the application of special treatment, since this will be unlikely to affect the overall objective of the legislation yet can impose a disproportionate burden on SMEs;
- § Size-related and temporal exemptions, though effective in some circumstances, must be implemented with care since they can compromise the overall objective of the legislation by excluding large numbers of businesses. In some areas – for instance Directive 2002/73 (equal treatment for men and women) – the compromise would be unacceptable since a two-tier system would be created and the principle in question would be undermined. Exemptions may be suitable where SMEs make up a relatively small part of the ‘problem’ that legislation seeks to address – for instance under Directive 2005/60 (money laundering and terrorist financing) where financial transactions are very small (likely to be the case for many micro-businesses). As noted above in Section 3.1.4, experts, including those from businesses groups such as UEAPME, have concerns about the use of exemptions for SMEs.

**Table 3.7: Suitability of the application of SME specific measures to selected pieces of EU legislation**

Legislation	Suitability of SME specific measure			
	Size-related exemptions	Temporal exemption	Special treatment	Tailor-made information, guidance
Directive 91/533 (employer's obligation to inform employees of contract conditions)	<b>Low</b> – unacceptable for any firm to be excluded or the integrity of the legislation would be compromised	<b>Low</b> – compliance systems would not take long to implement so there would be little value gained in a temporary exclusion period	<b>Medium</b> – reporting requirements could be relaxed for SMEs (e.g. a longer notice period)	<b>Medium</b> – affects a large number of firms, many of whom would be unlikely to be aware of the implications of the legislation and would benefit from awareness raising
Directive 2005/60 (prevention of the use of the financial system for money laundering and terrorist financing)	<b>Medium</b> – very small credit businesses are unlikely to process many financial transactions, though this must be balanced against security concerns	<b>Medium</b> – possibility for a short transition period for very small businesses in order to give them time to adapt whilst external reporting systems are set up	<b>Medium</b> – possibility of a ‘two-stage’ reporting with limited initial data submission, with an obligation to provide more information on request	<b>Low</b> – affects a relatively small number of businesses, and data reporting requirements are relatively straightforward
Directive 2002/73 (equal treatment for men and women for access to employment, vocational training and promotion, and working conditions)	<b>Low</b> – unacceptable for any firm not to provide for equal treatment for men and women in the workplace	<b>Low</b> – compliance systems would not take long to implement so there would be little value gained in a temporary exclusion period	<b>High</b> – reporting requirements could be relaxed for SMEs (e.g. provision of gender policy only on demand, and with a longer notice period)	<b>High</b> – a standard template for a gender policy together with good practice guidance would significantly reduce the burden for SMEs
Directive 95/46 (protection of individuals with regards to the processing of personal data)	<b>Low</b> – unacceptable for any business to compromise on personal data security	<b>Medium</b> – possibility for a short transition period for very small businesses in order to give them time to adapt whilst external reporting systems are set up	<b>Medium</b> – notification requirements could be made easier for SMEs, provided this did not compromise the integrity of the legislation	<b>Medium</b> – the requirements of the legislation are time-consuming rather than complex. However there may be need to inform businesses given the broad coverage of the legislation
Directive 2002/92	<b>Medium</b> – possibility that	<b>Medium</b> – possibility for a	<b>Medium</b> – notification	<b>Low</b> – affects a relatively small

Legislation	Suitability of SME specific measure			
	Size-related exemptions	Temporal exemption	Special treatment	Tailor-made information, guidance
(insurance mediation)	very small businesses might be excluded if they make up a very small proportion of the market	short transition period for very small businesses in order to give them time to adapt whilst external reporting systems are set up	requirements could be made easier for SMEs, provided this did not compromise the integrity of the legislation	number of businesses, and data reporting requirements are relatively straightforward
Directive 2006/12 (waste and recycling)	<b>Low</b> – whilst very small firms might not generate as much waste, the objective of the legislation is compromised if any business is excluded	<b>Medium</b> – compliance costs would be high and thus a transition period would be beneficial, provided it did not compromise the integrity of the legislation	<b>Low</b> – costs are generally generated by compliance, and could not therefore be reduced	<b>High</b> – affects a large number of firms, many of whom would be unlikely to be aware of the implications of the legislation and would benefit from awareness raising. Also support with waste reduction and recycling
Directive 2003/108 (waste electrical and electronic equipment)	<b>Low</b> – whilst very small firms might not generate as much waste, the objective of the legislation is compromised if any business is excluded	<b>Medium</b> – compliance costs would be high and thus a transition period would be beneficial, provided it did not compromise the integrity of the legislation	<b>Low</b> – costs are generally generated by compliance, and could not therefore be reduced	<b>High</b> – affects a large number of firms, many of whom would be unlikely to be aware of the implications of the legislation and would benefit from awareness raising. Also support with waste reduction and recycling
Directive 1999/31 (landfill of waste)	<b>Low</b> – whilst very small firms might not generate as much waste, the objective of the legislation is compromised if any business is excluded	<b>Medium</b> – compliance costs would be high and thus a transition period would be beneficial, provided it did not compromise the integrity of the legislation	<b>Medium</b> – there would be merit in exploring whether reporting requirements could be relaxed for very small businesses that would be unlikely to generate as much waste	<b>High</b> – affects a large number of firms, many of whom would be unlikely to be aware of the implications of the legislation and would benefit from awareness raising. Also support with waste reduction

### 3.4 The use of SME specific measures in EU programmes

Following the initial screening of programmes during the inception phase and the discussions with the Steering Group, five EU programmes were reviewed in order to assess the application of Think Small First (see Annex 2 for details). The results from this exercise are summarised below.

#### 3.4.1 Requirements for obtaining funds

While there is a need for internal and external control of the way in which Community funds are spent, the access requirements for obtaining funds can present a barrier for SMEs. In a working document on the simplification of the FP7<sup>25</sup> it was for example recognized that '*participation in FP6 remains complex for non-administrators and in particular for smaller actors*'. During the review it was therefore investigated what kind of requirements are to be complied with for applicants to the various programmes.

The review showed that basic eligibility criteria for the funding programmes are usually uncomplicated (such as requirements on being a legal entity within the EU). Moreover, sometimes previous experience or activity during a certain amount of time is required. In applications for funds, however, very detailed information usually needs to be submitted. Examples are proof of adequate financial and technical capabilities, detailed project descriptions and detailed budgets. Programmes also regularly require cooperation partners, sometimes in other Member States, or company consortia. These requirements add a new level of complexity with potential disproportionate effects on SMEs.

#### 3.4.2 Measures targeting SMEs

As set out in the 'Modern SME policy'<sup>26</sup>, SME participation in Community programmes can be increased by reducing the complexity of rules and procedures, improving information to SMEs on existing programmes and ensuring that evaluation procedures take into account the particularities of SMEs. During the expert workshop, attendees unanimously agreed on the fact that SME specific measures should be included systematically in EU programmes. Using a typology developed based on '*Models to reduce the disproportionate regulatory burden on SMEs*' the type of measures used in programmes can be summarized as follows:

- § *SME participation targets/monitoring* – there are set goals for SME participation and/ or the SME participation in the programme is specifically monitored;
- § *Special treatment* – SMEs are granted some form of special treatment, such as higher funding rates or prioritisation when grants are awarded;
- § *Tailor-made information, guidance and support services* – specific SME information points, portals and guides;
- § *Simplification of requirements* – administrative and financial rules and procedures are simplified.

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<sup>25</sup> COM(2005) 119 Commission Staff Working Document Simplification In The 7th Framework Programme

<sup>26</sup> COM(2005) 551 *Op cit.*

The review showed that while all programmes include an SME consideration, only FP7 and the ECO-Innovation Programme within the CIP actually have specific SME measures (see Table 3.8).<sup>27</sup>

The Framework Programmes for research have included initiatives for SMEs, such as SME specific schemes and monitoring of SME participation, for some time. Under FP6 for example, a range of Economic and Technological Intelligence (ETI) actions were funded aiming at helping SMEs in specific sectors to take part in FP6's mainstream research projects. They were aimed at intermediaries, such as SME National Contact Points, industrial federations, professional associations and chambers of commerce and aimed at gathering, analysing and disseminating information on technological developments, applications and markets relevant to SMEs. An impact assessment for improving SME specific research schemes<sup>28</sup> found that the ETIs had '*a strong structuring effect by leading many SMEs to propose a project for, and eventually participate in, the EU programmes*'.

The SME focus was further developed in FP7; the programme explicitly takes account of SMEs both as participants and beneficiaries of the results achieved by the programme. As part of general work to simplify the Framework Programme, a '*sounding board of smaller actors*' was set up with the aim of removing or reducing the barriers faced by small players participating in FP7. Other SME measures include SME participation targets and monitoring (an aim for at least 15 per cent of funding under the '*Cooperation*' sub-programme to go to SMEs), higher funding rates for SMEs (a maximum of 75 per cent of eligible costs instead of 50 per cent), 61 National Contact Points specifically for SMEs and *Techweb*: a dedicated website for SMEs in FP7. The Commission's information brochure on FP7<sup>29</sup> contains a section on benefits of each action to industry and SMEs and the '*Capacities*' sub-programme contains a specific strand for research for the benefit of SMEs.

As for the other reviewed programmes, Think Small First is less evident and less well documented. The ECO-Innovation programme is open for all companies; however priority will be given to SMEs when awarding grants. The legislative base for the MEDIA programme<sup>30</sup> specifies that SMEs should be supported, particularly with funds for development and distribution. Furthermore, the '*Development*' action of the programme is designed to meet the needs of small and medium sized production companies, but no specific measures for SME applicants were included. Similarly, ESF and Leonardo da Vinci do pay specific attention to SMEs but do not include any specific SME measures.

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<sup>27</sup> In this respect it should be noted that the analysis is based on what was found during the desk research. In practice, there may be measures to facilitate SME access or special consideration of SMEs when awarding grants, however these are not formalized in the documents reviewed.

<sup>28</sup> EPEC (2006) Impact assessment for improving SME specific research schemes and measures to promote SME participation in the framework programme

<sup>29</sup> [http://ec.europa.eu/research/fp7/pdf/fp7-factsheets\\_en.pdf](http://ec.europa.eu/research/fp7/pdf/fp7-factsheets_en.pdf)

<sup>30</sup> Decision No 1718/2006/EC of the European Parliament and of the Council of 15 November 2006 concerning the implementation of a programme of support for the European audiovisual sector (MEDIA 2007)

**Table 3.8: Overview of SME measures in the EU programmes reviewed**

<b>Programme</b>	<b>Includes SME consideration?</b>	<b>Includes SME measure?</b>
MEDIA 2007	The legislation text mentions that particularly SMEs should be supported, particularly with funds for development and distribution	No
FP7	SME consideration throughout the programme	SME participation targets/ monitoring, Preferential treatment, Simplified obligation, Tailor made information, coaching, training
ESF	The new ESF interventions will focus on giving direct assistance to companies and especially SMEs	No
ECO-Innovation Programme (CIP)	Priority will be given to SMEs, through call open for all legal persons	Particular attention
Leonardo da Vinci	Legislation text recognizes the importance of improving the attractiveness of Community action for SMEs	No

The rationale for a specific SME consideration is explicit in the majority of these programmes and includes reasons such as SMEs role in the economy and a wish to increase SME participation to the programme and the activities funded by it.

## 4 CONCLUSIONS AND RECOMMENDATIONS

This section of the report presents the conclusions of the study team in respect of the evaluation questions set out in the Terms of Reference and presented in Section 2.1.

### 1. *To what extent have the specific rules for SMEs contributed towards rendering the legislation more SME friendly?*

The focus of this study has been the application of SME specific measures in EU legislation. Of course, legislation can be made SME friendly without resort to the application of such measures, in line with the principles of Think Small First, and more generally in accordance with the Better Regulation agenda. During the drafting of legislation, minimising the scale of the administrative and compliance costs imposed on businesses – often felt disproportionately by SMEs – is, in effect, an application of the Think Small First principle. In terms of the process of drafting legislation, impact assessment and consultation with SMEs and business groups can ensure that legislation takes account of the needs of SMEs. Such applications of Think Small First have not been evaluated in this study, and indeed will generally not be apparent in the text of the legislation.

With these points in mind, this study identified 83 pieces of EU legislation that included specific reference to SMEs, which constitutes a very small proportion of all of the EU legislation in force (though as noted above this does not equate to the application of the Think Small First principle more broadly). Of the 83 pieces of legislation reviewed, 47 per cent contained some form of SME specific measure, whilst the remainder only included a reference to SMEs (e.g. a need to reduce the scale of the associated burden, but with no indication as to how this would be achieved). Whilst the use of SME specific measures in EU legislation is, therefore, not common, most measures were introduced recently (55 per cent date from 2001 onwards), suggesting a growing awareness of the value of including such measures in EU legislation.

Assessing the effectiveness of these SME specific measures – and the extent to which they have made legislation more SME friendly – is challenging. Few pieces of legislation specified why the needs of SMEs had been addressed, or what the SME specific measures were intended to achieve. Often there was a general aim to reduce the administrative burden for SMEs, but there was rarely an indication of how this was to be achieved, or an estimate of the extent to which the burden would be reduced. Where other objectives were included – for instance to increase SME participation in a scheme – again there were no targets specified which would assist as part of an assessment of the progress that was made (the exception was the FP7 programme which contained a target for SME participation in the ‘Cooperation’ sub-programme of 15 per cent). **In the future, in order to assess the effectiveness of the application of Think Small First there would be merit in establishing a more systematic arrangement for monitoring and evaluating the progress made with regard to the measures included in the legislation. Formulating clearer objectives for what is to be achieved with the Think Small First principle and setting up mechanisms for follow-up would be helpful in assessing to what extent the measures are effective.**

### 2. *What are the barriers to the effective implementation of specific rules for SMEs?*

In general, responsibility for the implementation of the SME specific measures was devolved to the Member States. Systematically assessing the effectiveness of this process was beyond the scope of this study given the number of pieces of legislation that included SME specific measures. Overall, however, **analysis of the legislative texts would suggest that a potential barrier to effective implementation was the lack of clarity as to how Member States were to operationalise the SME specific measures.**

Some 53 per cent of the 83 pieces of legislation reviewed as part of the study included a reference to the fact that the implementation of the legislation should take account of the needs of SMEs and not impose an undue burden, but did not specify how this was to be achieved. In other cases, legislation indicated which SME measure might be included, but left Member States to decide whether to take up this option. For example, Directive 2001/45 (minimum health and safety requirements for the use of work equipment at work) gave Member States the right to make use of a transitional period of two years, but did not stipulate that this exemption had to be introduced. Some pieces of legislation allowed Member States to decide how SME specific measures should be defined and implemented. Directive 2002/14 (a general framework for informing and consulting employees) left Member States to decide which employment thresholds to use in order to define which businesses could be exempted from the requirements of the legislation.

In light of the devolution of the implementation of the SME specific measures, the main barrier to their effectiveness will arguably be the different approaches taken by the Member States. Where a national authority or government department does not see the value in introducing or implementing SME specific measures, then the flexibility accorded to them through most pieces of EU legislation means that they would not have to. The case studies presented in Section 3.3 illustrate this point. Directive 96/34 (a framework agreement on parental leave) allows for special arrangements for 'small undertakings', providing national legislators with the right to grant exemptions or reductions in parental leave (thus potentially reducing compliance costs for SMEs). However, of the countries that responded to the request for information, none had taken up this option.

Differences in legal systems and lawmaking between Member States also have an impact on the way in which the SME specific measures are implemented. At the national level, lawmaking may be characterised by the traditional image of large 'national champion' firms. Moreover, there may not be any obligation to carry out impact assessments or consult business stakeholders, and even when there is a requirement, the processes may not necessarily be carried out properly.

*3. Are there any aspects, means or actors that render some of the specific rules for SMEs more or less effective than others?*

There are important variations between the SME specific measures that affect how effectively they operate when implemented. As Section 3.2.2 discussed and as the attendees of the expert workshop made clear, **SME specific measures cannot be applied across all policy areas with the same level of effectiveness.** The strengths and weaknesses of each of the types of SME specific measure are explored in more detail in the toolkit for legislators and policy-makers that is presented in Section 5.

Regarding size-related exemptions, some resistance has been voiced relating to the notion of 'exemption'; the argument being that it creates an image of SMEs not complying fully with regulation. Such resistance may affect the effectiveness of implementation within Member States. A lack of data is a particular barrier for applying reduced fees, as without this it is difficult to know what level of fee or reduction that is the most effective in reaching the goals of the measure. **It is also necessary to consider whether SME specific measures work effectively in isolation, or whether they are best suited to working in combination.** Temporal exemptions, for example, may be introduced by legislators in order to give SMEs time to adapt to enhanced compliance requirements (for example the need to install new equipment or set up new reporting systems). In order to be effective, the length of these exemptions needs to be assessed in order to ensure that SMEs have enough time to adapt (without providing too much time and undermining the overall purpose of the legislation), and it may be necessary to establish a complementary support service providing guidance (such as training) and information (standard templates for reporting, for example).

The role of actors is an important influence on the effectiveness of the SME specific measures. As noted above, the attitudes of legislators and policy-makers towards the SME specific measures are important given the devolved nature of implementation. Services such as helpdesks require national authorities to allocate financial and human resources in support of the application of SME specific measures; without the commitment of the Member States the effectiveness of these activities will be reduced.

At the same time the effectiveness of Think Small First depends on dialogue between stakeholders. Good practice and innovation in the assistance provided to SMEs is often generated at the level of the Member States (as demonstrated by the report on *Models to reduce the disproportionate regulatory burden on SMEs*). **The European Commission has an important role to play in organising the collection, exchange and wider dissemination of this good practice.** In order to ensure that the views of businesses regarding the effectiveness of SME measures are understood, there is also an important role for intermediary business organisations in collecting feedback and ensuring that legislators within the European Commission and the Member States are made aware of any issues.

Finally, the effectiveness of the SME specific measures is affected by the SMEs themselves. Helpdesks and support services will only make a difference if businesses make use of the service available. Other SME specific measures require a degree of pro-activeness on the part of businesses in order to register or make the authorities aware that they are eligible. In this context **awareness raising** is important in order to ensure that SMEs are aware of the measures available to them, be it through dissemination on the part of business organisations, or government measures such as introducing all legislation on a single date.

#### 4. *To what extent does the EU have a coherent approach to specific rules for SMEs?*

The analysis of the application of SME specific measures in EU legislation presented in Section 3.2 indicated a **lack of overall consistency or coherence in the EU's approach.** To some extent a lack of coherence is inevitable given the fact that the use of SME specific measures spans a considerable time period (as far back as 1972), and crosses policy areas and Directorates-General. However, whilst it has not been

possible to explore these issues with national authorities, intuitively a lack of clarity and consistency could act as a barrier to effective implementation.

There are a number of examples of this lack of coherence, firstly in terms of the **definition of what constitutes an SME**, and thus to which businesses the specific measures should apply. A number of pieces of legislation referred to the Commission's definition of an SME<sup>31</sup>, but in most cases there was either no definition or the thresholds used to define an SME were different from those contained in the Commission's official definition (such as under Directive 2002/14 establishing a general framework for informing and consulting employees where a threshold of at least 20 employees was used). Directive 70/156 (type approval for motor vehicles) applied an exclusion on the basis of the size of a production run (500 cars placed on the market in a year) which by extension will benefit SMEs, but is not defined as such. Other pieces of legislation referred to 'small producers' or 'small retailers' without indicating what this meant.

Secondly, there was also a **lack of coherence in terms of which SME measures were applied to particular policy areas, or to tackle particular types of compliance or administrative burden**. A clear example concerns the application of reductions in the fees that SMEs have to pay to European agencies. There are a total of 24 European agencies, many of which provide a service to businesses (for example by certifying that products can be placed on the European marketplace). The activities of these agencies is controlled to varying degrees by the European Commission, yet there is no consistency in how SMEs are treated. In respect of the European Medicines Agency, Regulation 2049/2005 regarding the charges levied by the Agency for its services stipulates that SMEs are eligible for reduced fees. However, Regulation 6/2002 regarding the registration of Community designs at the Office for Harmonisation in the Internal Market contains no such fee reduction for SMEs.

Of course, the SME specific measure cannot be implemented as a one-size-fits-all model for making legislation more SME friendly, and the differences between pieces of legislation (their goals, scope and methods of implementation) mean that SME specific measures will always need to be tailored according to circumstances. Nevertheless, at present there is a lack of an overall coherence and consistency within EU legislation that suggests that SME specific measures are not universally understood or applied at either an EU or national level. Moreover, the impact of these variations on businesses and markets can be significant; a company may benefit from a size-based exclusion in one country but not in another with potentially distorting effects on the operation of the single market.

*5. How coherent are these specific rules for SMEs within the aims and implementation arrangements for each piece of legislation?*

In some of the pieces of legislation reviewed in this study, the rationale for the inclusion of one or more SME specific measures was clearly stated. A number of examples are found among legislation regarding statistics, where an intention to **reduce the scale of the administrative burden** translated into size-related exemptions or simplified reporting requirements. Elsewhere, in the pharmaceutical and medicinal sector legislation such as Regulation 141/2000 (orphan medicinal products) and Regulation

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<sup>31</sup> Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises

1394/2007 (advanced therapy medicinal products), support measures were introduced with the **aim of increasing SME involvement in research and innovation**. In these cases the coherence or intervention logic of the SME support measures was clear and the context within the overall aims for the legislation was sound.

In general, however, the internal coherence of the application of the SME specific measures was much less clear. Legislation rarely explained why SME specific measures were included, what their aims were, and how they related to the overall aims and implementation arrangements for the legislation. Key to ensuring a greater sense of consistency would be a **greater emphasis on evidence-based legislation that clarifies rationales and includes a quantitative assessment of why particular SME specific measures have been selected, and how the levels of any thresholds** (reduced fees, temporal exemptions, size-based exemptions) **have been set**.

As noted previously, the **roles and responsibilities of the implementing authorities** were also rarely specified, which could be problematic where legislation was the responsibility of government departments that were unfamiliar with the challenges faced by SMEs. Case study evidence provides further detail on the overall coherence where the implementation of SME specific measures was devolved to national authorities. In respect of Directive 2006/112 (the VAT Directive) the possibility of exempting certain taxpayers had been picked up by all five of the Member States that responded to the request for information. Regarding Regulation 761/2001 (the EMAS scheme) there were differences between Member States as to what extent the possibilities provided by the EU level legislation were used. The least coherence was found in the framework agreement on parental leave, where there was only two examples from the respondent Member States of the application of an SME specific measure.

6. *What aspects of the specific rules for SMEs are the most efficient or inefficient? What does this represent in terms of administrative and reporting burdens?*

At present there is **insufficient monitoring and evaluation data on the implementation and results of the SME specific measures to enable an assessment of absolute or relative efficiency**. In any case, operationalising the concept of efficiency would be difficult in respect of the SME specific measures, since calculating management and implementation costs – for national authorities and for SMEs – would be problematic. Certain SME specific measures would impose additional management costs; support services for SMEs, for example, would have to be funded using either EU or national resources. Measuring and benchmarking the efficiency of such a service, however, would be extremely difficult given the absence of suitable metrics. It is also possible that SME specific measures would impose additional costs in terms of enforcement as national authorities would have to verify that businesses were eligible.

7. *To what extent could measures be taken to improve the utility of the Think Small First principle? What lessons learned from the implementation of the specific rules for SMEs are useful for the implementation of the Think Small First principle?*

As a final stage in the evaluation of Think Small First, **a toolkit has been developed** with the aim to assist those developing new or revised legislation and other EU measures to anticipate potential negative effects and to design measures in such a way that the benefits of the measures are maximised whilst the costs to SMEs are

minimised. The toolkit is outlined in Section 5 and is **designed to complement the Commission's Impact Assessment guidelines** (including the public consultation document produced as part of the ongoing revision of the guidelines)<sup>32</sup>, in particular when analysing potential impacts on SMEs (through, for instance, the '**SME test**').

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<sup>32</sup> European Commission – Impact Assessment Guidelines [Draft version 27/05/2008]

## 5 A TOOLKIT FOR THE APPLICATION OF THE THINK SMALL FIRST PRINCIPLE

Applying the Think Small First principle means considering SMEs' interests at the earliest stage of policy making. This process should ensure that legislation and programmes are adapted to meet the specific situation of SMEs, which, in turn, should enable the alleviation of the burden for SMEs to a reasonable and proportionate level whilst achieving the objectives of the legislation or programme (as well as laying the basis for improved monitoring of the effect on SMEs).

The toolkit set out below assumes that, in addition to specific rules for SMEs, policy options that are alternatives to 'traditional' legislative and funding mechanisms are possible. These alternative policy options might include: self regulation, co-regulation, and market based instruments.

### 5.1 The scope of the toolkit

The focus of the toolkit is on EU interventions, including:

- § EU legislation: Regulations, Framework Directives and Directives;
- § EU funded programmes: including those both directly and indirectly targeted at SMEs;
- § Measures to encourage the development of SME policies in Member States, through the Open Method of Coordination (OMC) and actions to encourage cross border cooperation and exchanges.

The definition of SMEs used in the toolkit is the official EU definition. Where appropriate a distinction is made between medium-sized companies (50-250 employees), small-sized companies (10-49 employees), and micro-companies (fewer than 10 employees).

The toolkit considers the following issues, each of which is described below:

- § Why is it useful and relevant to Think Small First?
- § What are the anticipated benefits and costs of EU interventions?
- § What are the key effects on SMEs in different policy areas?
- § Which SMEs are affected by EU interventions?
- § How can Think Small First be applied to different types of EU intervention?

### 5.2 Why is it useful and relevant to Think Small First?

There are a number of arguments for applying the Think Small First principle to EU legislation and programmes:

- § SMEs constitute 99 per cent of all enterprises in the EU. If an EU intervention works well with respect to SMEs, it should work well for all companies;
- § SMEs are an important driver of economic growth; they produce more than half of European GDP and account for two thirds of the jobs in the private sector.

The relaunched Lisbon agenda identified SMEs as the main engine that would bring higher growth and more jobs in Europe, and the recently adopted European Small Business Act also contains a number of measures intended to ensure the prosperity of SMEs (including an objective to design legislation according to the principles of Think Small First). Data from Eurostat show that, between 2001 and 2003, where there have been net employment gains, the growth in employment was higher among SMEs than among large enterprises;

- § The costs of meeting administrative and compliance requirements of EU legislation and measures are disproportionate for SMEs, and this could inhibit their growth. The last analytical report of the Observatory of European SMEs stated that, apart from limitations on the demand side, the most important individual business constraint reported by SMEs was compliance with administrative regulations. Some 36 per cent of European SMEs reported that this issue had constrained their business activities over the previous two years;

Given these arguments, failure to apply the Think Small First principle could mean that the costs of business compliance with EU legislation outweigh the benefits.

### 5.3 What are the anticipated benefits and costs of EU interventions?

It is useful to consider the direct and indirect beneficial changes and effects that the EU intervention would bring to SMEs. These benefits reflect the public policy aims of the EU measure in question.

The (types of) **direct** benefits to SMEs include:

- § Improved safety;
- § Reduced unfair competition;
- § Improved energy efficiency;
- § Improved working conditions (productivity)
- § Reductions in fraud by competitors
- § Increased R&D investment; and,
- § Improved investments in human resources.

These direct benefits should (at some stage) be reflected in reduced costs to SMEs. (In most circumstances most SMEs within the EU will already be complying with the requirements envisaged within EU legislation either because of national legislation or because the SME itself considers that the benefits of doing so outweigh the costs).

The (types of) **indirect** benefits that accrue to society and the economy in general as well as to SMEs include:

- § The realisation of economic potential of SMEs;
- § Improved environment;
- § Rural and regional convergence and cohesion;
- § Improved security;
- § Improved consumer protection;
- § Improved social protection;

- § Improved skills of the working population; and,
- § Improved policies and practices at national regional and local levels.

These benefits may be offset by the following types of costs, some of which can be disproportionately felt by SMEs:

- § *Administrative costs*: in particular, the costs associated with reporting to government agencies to generate statistics or for other purposes. Such activities may generate 'one off' costs that are proportionally higher for smaller companies and of little or no direct benefit to them;
- § *Compliance costs*: these are typically the costs incurred as a consequence of legislation, but could also accrue through voluntary regulation. Compliance costs are typically associated with: physical changes within company premises (e.g. access for those with disabilities); procedures relating to products (safety validation, labelling etc.); procedures relating to processes, (company law, access to finance, pre contract information, withdrawal period, guarantees, working practices, employment law etc). Such costs may be proportionally higher for smaller companies. In most instances compliance should be associated with benefits to the SME (e.g. access to new markets as a result of compliance with EU-wide standards);
- § *Cost associated with legal uncertainty*: legal uncertainty is an important factor in influencing the behaviour of all companies and SME in particular. EU legislation has the potential to reduce or increase legal uncertainty which can arise through differences in law between countries and weaknesses (e.g. varied definitions) in laws;
- § *Transaction costs*: all business transactions incur transaction costs, such costs may be disproportionate for SMEs wishing to access EU programmes and/ or participate in public procurement. The costs include: the time and resources required to acquire information on the possibilities available; the time and resources to make tenders and applications (including unsuccessful applications); the financial requirements of participation (co-financing, guarantees etc); and, the time and resources to report (e.g. audit requirements). The nature of the procedures may pose challenges and impose costs that are disproportionate to SME that would be participants in programmes and public procurement.

It is relatively straightforward to measure administrative costs; the Standard Cost Model (SCM) exists for this purpose. For example, a recent report published by the Department for Business, Enterprise and Regulatory Reform in the UK used the SCM to estimate the regulatory 'burden' associated with 41 pieces of EU legislation identified by the European Commission as particularly suitable for reform<sup>33</sup>. The total cost associated with these 41 pieces of legislation in the UK was calculated as €3.8 billion.

Regarding compliance costs, whilst the SCM may be a useful tool, measuring the net costs of compliance is difficult. Evidence from companies that are already in compliance can provide some indication of the extent to which compliance is beneficial

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<sup>33</sup> Department for Business, Enterprise and Regulatory Reform (2008) 25 ideas for simplifying EU law

to companies. Measuring costs of legal uncertainty is also very difficult, but surrogates such as the costs of legal advice can be used (these are typically proportionally higher for smaller firms). Estimating the scale of transactions costs can be done using the SCM.

Box 5.1 shows key questions and information needed to help identify the benefits and costs to SMEs of EU interventions. It can be useful to depict the benefits and costs in an intervention logic, distinguishing between the different types of costs.

**Box 5.1: Key questions for the assessment of benefits and costs to SMEs of EU interventions**

What are key direct benefits to SMEs (are SME already complying, what benefits have accrued to them)?

In what way does the proposal introduce administrative costs; what are the estimated costs of these?

In which manner does the proposal affect compliance costs?

In which manner does the proposal reduce or increase legal uncertainty?

In which manner does the proposal generate transaction costs to SME?

#### 5.4 What are the effects of legislation on SMEs?

The review of EU legislation carried out in the study provided examples of the legislative requirements imposed on companies (see Annex 1 for details). Many of these are felt disproportionately by SMEs where, for example, costs are fixed and thus do not increase with firm size. Legislative effects vary by policy area:

- § *Employment conditions*: physical changes (e.g. providing access for those with disabilities); reporting, registering and keeping records (e.g. on working time); providing both physical and financial means for consultations; and, providing training;
- § *Occupational health and safety*: product testing; meeting hygiene standards; physical changes and related capital investment; staff resources; training, procedures; carrying out and keeping records of risk assessments; providing protective equipment;
- § *Consumer protection*: costs of entering different markets; providing information (on terms of contract, labelling) to consumers and authorities;
- § *Environment*: recording and reporting; informing consumers and authorities; collection and recycling of waste; obtaining licences and permits; adaptation of processes/ facilities (e.g. to comply with emissions restrictions);
- § *Taxation*: reporting; accounting; adjustments of internal systems;
- § *General Internal Market rules*: obtaining permits for specific products; meeting standards; certification; reporting; labelling.

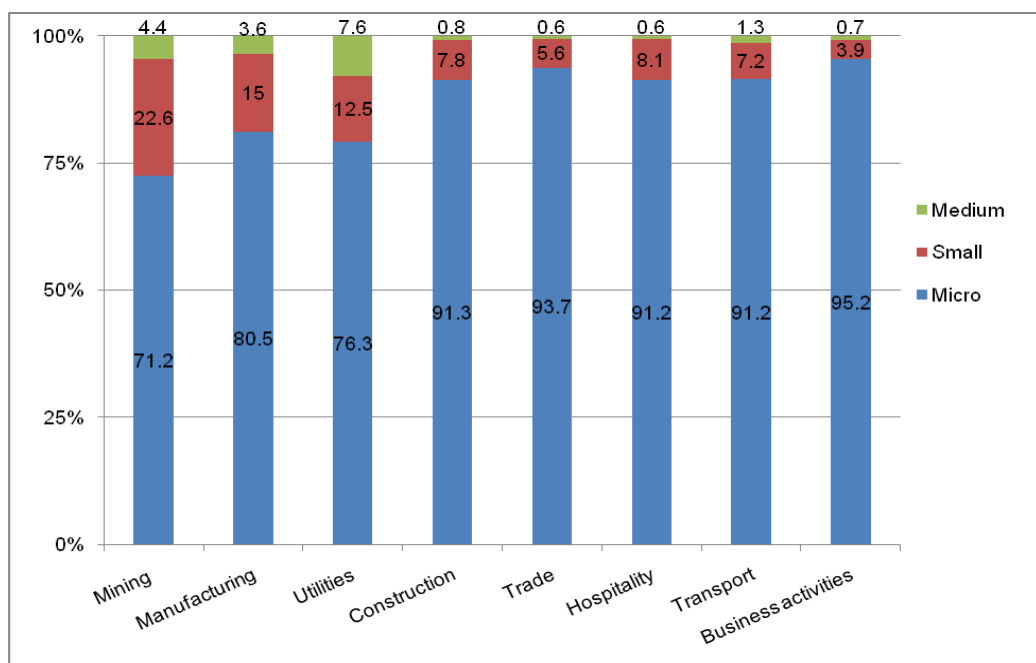
#### 5.5 Which SMEs are affected by EU interventions?

Legislation affects SMEs in different ways. For many interventions, the absolute costs of administrative and compliance requirements for SME are the same or similar to those of larger companies and hence potentially disproportionate (where larger firms

are able to benefit from economies of scale). Thus where an intervention affects a particular economic sector it is useful to consider the extent of concentration of output/employment in SME and larger companies and the numbers of SME of different sizes (small, medium and micro).

Figure 5.1 below depicts the share of small-, medium- and micro-sized companies in different economic sectors.<sup>34</sup> As can be seen, micro enterprises make up the majority of the business stock in all of these sectors. Micro and small companies are likely to be disproportionately affected by the administrative and compliance effects of legislation in comparison to medium sized firms.

**Figure 5.1: Size distribution of enterprises by economic sector, EU-27, 2005**



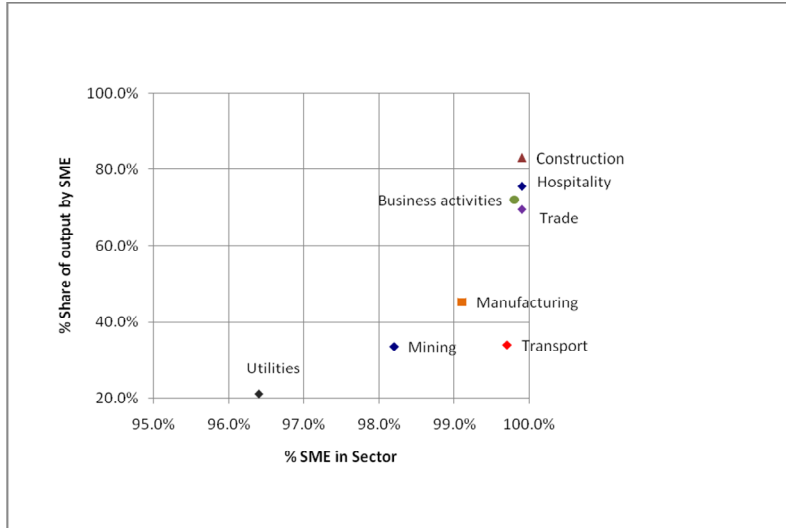
Source: Eurostat SBS

The aggregate impact of the effect of legislation on SMEs varies according to the industrial sector and thus legislation should be designed to fit the particular sectoral characteristics. Figures 5.2 and 5.3 show SME share of total sectoral output and employment, plotted against the proportion of SMEs in that sector. In some sectors (e.g. utilities and mining) SMEs make up a small proportion of the total business stock, employ relatively few people and make a relatively small contribution to EU output. Legislative effects on SMEs may place SMEs at a disadvantage vis-à-vis larger firms, but the overall net impact on EU output and employment would be relatively low.

Conversely, in sectors where SMEs make up a large proportion of the business stock and are responsible for relatively large proportions of employment and output (e.g. construction, hospitality, services and retail), the overall net aggregate impact of legislation affecting SME's on the EU economy may be higher.

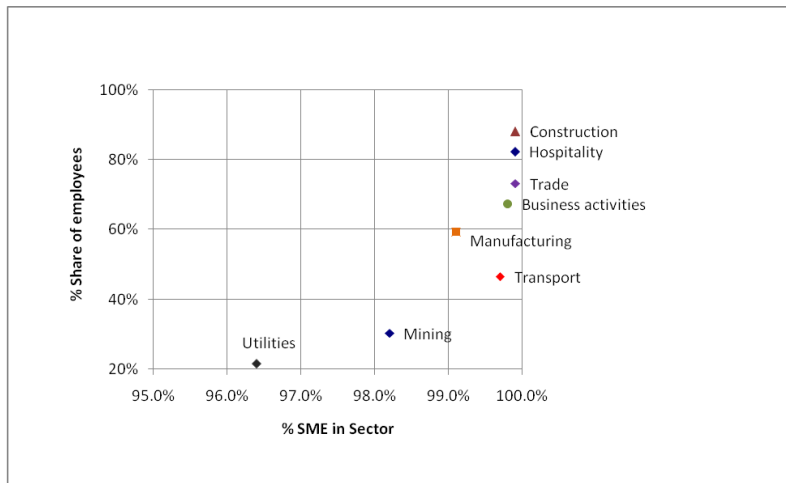
<sup>34</sup> Large companies are not shown as their share of the total EU business stock is small (typically between 0.1 per cent and 3.6 per cent of the total)

**Figure 5.2: SME share of sector output and SME share in sector, 2005**



Source: Eurostat SBS

**Figure 5.3: SME share of employees in sector and SME share in sector, 2005**



Source: Eurostat SBS

It is also useful to consider how the business structure of the economic sectors is changing. In some sectors there may be a trend towards concentration of employment and output in larger companies that could itself be a combination of the need for economies of scale and/or driven by the requirements of legislation. (For example, the requirements to accident test vehicles may generate compliance costs that would be disproportionate to small car manufacturers. Similarly, the requirements for the testing of drugs may have encouraged concentration within the pharmaceuticals sector). On the other hand there may be economic sectors where technological and other factors are encouraging trends towards de-concentration.

It may also be useful to consider aspects of the integration between sectors and the character of supply chains. For example, if within a particular sector there is a strong measure of vertical integration with SMEs mainly providing goods and services to the

larger companies then the case for specific rules for SME may be less than if the integration is weak.

Finally, the SME definition embodies a very wide range of types of company. They range from the individual who has reluctantly entered self employment through experiencing difficulties accessing employment to a company employing just less than 250 employees but having in effect a global reach and plans for becoming a very large company. Between these extremes there are a multitude of variations in terms of size, orientation, ownership and market potential which need to be taken into consideration and could lead to a differentiation between micro, small and medium sized companies.

**Box 5.2: Key questions to determine which SMEs are affected by EU intervention**

How many SMEs and larger companies will be affected?

To what extent is the employment/output concentrated in SME of different sizes and larger companies?

What are the trends of concentration/ de-concentration within the sector?

To what extent is the economic sector vertically integrated?

## 5.6 How can Think Small First be applied to EU legislation?

The first priority in terms of the application of Think Small First should be to ensure that legislation is designed in such a way as not to impose an undue burden on SMEs. The European Commission's Better Regulation agenda includes good practice in the area, since it focuses on ensuring that the regulatory environment in Europe is business friendly through the simplification of existing legislation and the reduction, where possible, of administrative burdens<sup>35</sup>.

There are also a number of other ways in which the principles of Think Small First can be applied, including as part of the process through which legislation is developed and implemented. **Impact assessment and consultation** ensures that the needs of SMEs are taken into account during the drafting of legislation. As part of the principles of the new European Small Business Act, it is envisaged that an '**SME test**' will be used in the drawing up of any legislative proposal affecting businesses at an EU level, in order to assess the impact on SMEs.

In the UK all legislation affecting businesses is introduced on one of two dates each year, thus ensuring that businesses know when to check for legislative changes and can plan ahead accordingly. This approach is particularly relevant where legislation might affect a large number of businesses across sectors, and also where there are frequent changes to legislation (such as technical amendments). There are also non-legislative means to ensure that the burden placed on SMEs is not disproportionate through, for example, **self regulation, information campaigns and exchanges of experience** which can be particularly effective in situations where the enforcement of legislation is difficult.

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<sup>35</sup> COM (2008) 32 Second strategic review of Better Regulation in the European Union

On occasions, however, the **importance of other goals – health and safety, for example – may mean that legislation inevitably imposes compliance or administrative costs on businesses, some of which may disproportionately affect SMEs.** In such cases there may instead be a need to include provisions targeted at SMEs in order to mitigate or reduce the scale of the disproportionate burden. This report has evaluated the application of such SME specific measures in EU legislation. On the basis of these results there follows a review of each of the SME specific measures in turn, including an example of its application, an overview of the strengths and weaknesses, and a description of the circumstances where the application of the measure would be most appropriate.

**These measures should not be considered in isolation and it is possible that their effectiveness and impact could be enhanced if implemented in synergy.** The review of the inclusion of SME specific measures in EU legislation set out in Section 3.2 identified five cases where legislation included more than one measure, so at present this is clearly not a common approach. Nevertheless, combinations of measures – for instance temporal exemptions combined with tailor-made support in order to help SMEs adapt during the transition period – should be considered.

The following types of SME specific measure are described in the toolkit:

- § Size-related exemptions;
- § Temporal exemptions;
- § Special treatment (simplified reporting and reduced fees);
- § Tailor-made information, guidance and support;
- § Online services.

<b>SIZE-RELATED EXEMPTIONS</b>	
<p>Current <i>examples</i> of the application of the measure in EU legislation:</p> <ul style="list-style-type: none"> <li>§ <b>Directive 98/59</b> regarding <b>collective redundancies</b>: consultation procedures are only to be carried out if at least 10 dismissals are planned in companies with 20-100 employees;</li> <li>§ <b>Directive 72/221</b> regarding <b>annual surveys of industrial activity</b>: annual surveys are only to be carried out in enterprises employing more than 20 persons. Smaller firms only participate every five years.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Enforcement costs are relatively low;</li> <li>§ Easy to apply and easy for firms to understand;</li> <li>§ Potential for a significant reduction in</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Risk of threshold effects;<sup>36</sup></li> <li>§ May create market distortion in favour of SMEs;</li> <li>§ Excludes some businesses from the</li> </ul>

<sup>36</sup> Threshold effects are where the introduction of set values below which certain benefits apply (such as exclusion from certain legislative requirements) creates an incentive to remain below the threshold. For example, if a firm is exempt from legislation provided it does not employ more than 250 people, there would be an incentive to ensure that the threshold is not crossed, thus restricting employment growth.

<b>SIZE-RELATED EXEMPTIONS</b>	
<p>the regulatory burden on SMEs, particularly through reduced costs of compliance.</p>	<p>scope of the legislation and thus may undermine its purpose;</p> <p>§ By excluding some firms there is a danger of giving the impression that the aim of the legislation is not important, or that SMEs do not comply with the legislation.</p>
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <p>§ Where legislation is difficult to enforce (e.g. where it affects large numbers of SMEs);</p> <p>§ Where the consequences of the exclusion of SMEs from scope of the legislation are considered acceptable;</p> <p>§ Where the benefits of including SMEs would be small relative to the compliance costs imposed (e.g. where the output or contribution of SMEs to the ‘problem’ is relatively minor);</p> <p>§ Where the danger of market distortion in favour of SMEs is not a problem;</p> <p>§ Where legislation concerns procedures and processes (e.g. generates an administrative burden).</p>	

<b>TEMPORAL EXEMPTIONS</b>	
<p>Current <i>examples</i> of the application of the measure in EU legislation:</p> <p>§ <b>Directive 2001/45</b> regarding the <b>use of work equipment</b>: allows for a transitional period of two years to allow for SMEs in the construction sector to adapt to the legislation;</p> <p>§ <b>Directive 2002/15</b> regarding the <b>organisation of working time</b> of persons performing mobile road transport activities: legislation is not applicable for self-employed drivers until 2009.</p>	
<p><i>Advantages:</i></p> <p>§ Enforcement costs are relatively low;</p> <p>§ Easy to apply and easy for firms to understand;</p> <p>§ Flexible and applicable to many different policy areas.</p>	<p><i>Disadvantages:</i></p> <p>§ Danger of market distortion by giving SMEs an unfair advantage for a set period of time;</p> <p>§ Temporarily excludes some businesses from the scope of the legislation and thus may undermine its purpose;</p> <p>§ By excluding some firms there is a danger of giving the impression that the aim of the legislation is not important, or that SMEs do not comply with the legislation;</p>

<b>TEMPORAL EXEMPTIONS</b>	
	§ Could delay adaptation by SMEs.
<p><i>Circumstances</i> where the measure is likely to be <i>most effective</i>:</p> <ul style="list-style-type: none"> <li>§ Where legislation is difficult to enforce (e.g. where it affects large numbers of SMEs);</li> <li>§ Where the compliance costs are relatively or absolutely high and a ‘transition’ period would provide SMEs with time to adapt;</li> <li>§ Where the consequences of the exclusion of SMEs from scope of the legislation during the ‘transition’ period are considered acceptable;</li> <li>§ Where the benefits of including SMEs from the outset would be small relative to the compliance costs imposed (e.g. where the output or contribution of SMEs to the ‘problem’ is relatively minor).</li> </ul>	

<b>SIMPLIFIED REPORTING</b>	
<p>Current <i>example</i> of the application of the measure in EU legislation:</p> <ul style="list-style-type: none"> <li>§ <b>Regulation 638/2004</b> regarding <b>statistics relating to the trading of goods between Member States</b>: SMEs are allowed to provide less detailed information (e.g. report fewer goods classes).</li> </ul>	
<p><i>Advantages</i>:</p> <ul style="list-style-type: none"> <li>§ Potential to significantly reduce administrative requirements for SMEs;</li> <li>§ Applicable across all policy areas.</li> </ul>	<p><i>Disadvantages</i>:</p> <ul style="list-style-type: none"> <li>§ Reporting information is not collected for SMEs, possibly affecting the overall quality of statistical information; and of monitoring.</li> <li>§ By excluding some firms there is a danger of creating the impression that reporting requirements are not important.</li> </ul>
<p><i>Circumstances</i> where the measure is likely to be <i>most effective</i>:</p> <ul style="list-style-type: none"> <li>§ Where administrative and reporting costs are particularly high, and where the effects are disproportionate to SMEs (e.g. where the cost of the burden is fixed);</li> <li>§ Where the quality and usefulness of the information collected is not compromised by the exclusion of SMEs;</li> <li>§ Where reporting relates to information and statistics and is not part of compliance.</li> </ul>	

<b>REDUCED FEES</b>	
<p>Current <i>example</i> of the application of the measure in EU legislation:</p> <ul style="list-style-type: none"> <li>§ <b>Regulation 2049/2005</b> setting the <b>fees charged by the European Medicines Agency</b>: fees for inspections, scientific advice and scientific services are reduced</li> </ul>	

<b>REDUCED FEES</b>	
by 90 per cent for SMEs.	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Easy to implement and easily understood by SMEs;</li> <li>§ Potential to significantly reduce administrative requirements or transaction costs for SMEs, thus ensuring a level playing field where costs are 'fixed' and thus disproportionate to SMEs;</li> <li>§ Can be used to encourage SME participation in a market or scheme.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Risk of threshold effects;</li> <li>§ Possible market distortion in favour of SMEs;</li> <li>§ Difficult to use if the organisation charging fees is independent from EU/ government (where prices of private companies may not be dictated by public authorities).</li> </ul>
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Where fees are particularly high and/or represent a fixed cost that would be felt disproportionately by SMEs;</li> <li>§ In voluntary schemes where SME participation needs to be increased and where fees create a barrier/ disincentive to involvement;</li> <li>§ In relation to the fees charged by EU or other public sector agencies.</li> </ul>	

<b>TAILOR-MADE INFORMATION, GUIDANCE AND SUPPORT</b>	
<p>Current <i>example</i> of the application of the measure in EU legislation:</p> <ul style="list-style-type: none"> <li>§ <b>Regulation 1907/2006 (REACH):</b> Member States must establish national helpdesks in order to provide businesses with advice and support with implementation.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Can be designed and implemented to meet demand (e.g. used whilst legislation is new and phased out over time);</li> <li>§ Can easily be implemented alongside the other SME specific measures.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Potentially high cost and uncertainties over who pays (EU or Member States);</li> <li>§ Difficulties in ensuring that all SMEs are aware of the service and able to access assistance.</li> </ul>
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Where legislation is complex and likely to affect a large number of businesses;</li> <li>§ Where legislation is substantially changed or where existing legislation is amalgamated;</li> <li>§ Where the negative effects of non-compliance are highly significant.</li> </ul>	

<b>ONLINE SERVICES</b>	
<p>Current <i>example</i> of the application of the measure:</p> <ul style="list-style-type: none"> <li>§ An E-Depot in Belgium that allows new businesses to deposit their registration documents electronically.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Reduces cost and time spent on searching for information, filling in forms etc;</li> <li>§ Easy to access.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Risk of information overflow;</li> <li>§ Needs appropriate security measures to protect submitted information;</li> <li>§ Possible significant administrative set up or reorganisation costs in order to be effective.</li> </ul>
<p><i>Circumstances</i> where the measure is likely to be <i>most effective</i>:</p> <ul style="list-style-type: none"> <li>§ Standard, relatively simple procedures (e.g. company start-up or VAT registration);</li> <li>§ Where there is no need for face-to-face contact between businesses and authorities;</li> <li>§ Where the 'paper' costs of services are high and disproportionately felt by SMEs.</li> </ul>	

## 5.7 How can Think Small First be applied to EU programmes?

This study also investigated the application of Think Small First to EU programmes. Some of the measures described above can be adapted to programme procedures and administrative processes. The following tools for applying Think Small First to EU programmes are considered:

- § SME participation targets and monitoring;
- § Two-part application forms;
- § Pre-participation assistance; and,
- § Preferential treatment.

<b>SME PARTICIPATION TARGETS AND MONITORING</b>	
<p>Current <i>example</i> of the application of the measure:</p> <ul style="list-style-type: none"> <li>§ Aim of at least 15 per cent of funding under 'Cooperation' sub-programme of FP7 to go to SMEs.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Relatively easy to use as company size can be easily monitored (e.g. when applications are filed);</li> <li>§ Allows for subsequent follow up and evaluation, particularly of the</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ A passive measure as it does not actively affect SME participation in a programme on its own.</li> </ul>

<b>SME PARTICIPATION TARGETS AND MONITORING</b>	
efficiency of other SME measures that may be used in parallel.	
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Where there is an explicit intent and economic rationale to increase SME participation in a programme;</li> <li>§ Where other SME specific measures are used, in order to evaluate the efficiency of those measures.</li> </ul>	

<b>TWO-PART APPLICATION FORMS</b>	
<p><i>Description of the application of the measure:</i></p> <ul style="list-style-type: none"> <li>§ The first part of the form includes basic company data and a short project presentation. If the project is judged to qualify based on this initial information, a second, and more detailed, form is filled out by the applicant. A system like this is currently used as part of the FP7.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Detailed project information only has to be provided for projects that have a good potential of qualifying for a grant;</li> <li>§ The basic company information will not have to be provided again should the applicant apply for another grant/programme participation.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Initial project information may not be enough to judge whether project should be funded or not.</li> </ul>
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Complex application procedures where detailed information on the company and project/proposal is required;</li> <li>§ Where the same applicant can apply for several grants.</li> </ul>	

### **Pre-participation assistance**

Various forms of pre-participation assistance given to SMEs can be useful, particularly if programme requirements cannot be simplified. Examples include helpdesks, and the provision of online guidance and other forms of information provision.

<b>HELPDESKS</b>
<p><i>Current example of the application of the measure:</i></p> <ul style="list-style-type: none"> <li>§ There are 61 national contact points specifically for SMEs to assist their participation in the FP7.</li> </ul>

<b>HELPDESKS</b>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ The organisational structures are in place already as EU programmes typically have national contact points that assist programme participants. These can be tailored to the needs of SMEs;</li> <li>§ Can provide personalized assistance in the local language.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Resource intensive and thus high cost.</li> </ul>
<p><i>Circumstances where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Where application procedures are complex;</li> <li>§ Where funding requires partners in other countries.</li> </ul>	

<b>ONLINE GUIDANCE AND OTHER INFORMATION</b>	
<p>Current <i>example</i> of the application of the measure:</p> <ul style="list-style-type: none"> <li>§ The 'Techweb' site provides information to SMEs wanting to participate in research and the FP7.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Easy to access information and documentation;</li> <li>§ Relatively low cost;</li> <li>§ Easy to update.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Risk of 'information overflow';</li> <li>§ Risk of creating additional layer resulting in low visibility among target audience;</li> <li>§ Published material can become outdated quickly.</li> </ul>
<p><i>Circumstance where the measure is likely to be most effective:</i></p> <ul style="list-style-type: none"> <li>§ Can be applied for most EU programmes;</li> <li>§ Need for awareness raising.</li> </ul>	

### **Preferential treatment**

Various forms of preferential treatment can be used to Think Small First in EU programmes. Two examples that can be considered are higher funding rates and priority to SMEs when awarding grants.

<b>HIGHER FUNDING RATES</b>
<p>Current <i>example</i> of the application of the measure:</p> <ul style="list-style-type: none"> <li>§ In FP7, SMEs can receive a maximum of 75 per cent of eligible costs funded</li> </ul>

<b>HIGHER FUNDING RATES</b>	
instead of the usual 50 per cent.	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Can serve as an incentive for SMEs to participate in programme;</li> <li>§ Can increase SME participation.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Costly from a community perspective.</li> </ul>
<p><i>Circumstance</i> where the measure is likely to be <i>most effective</i>:</p> <ul style="list-style-type: none"> <li>§ Where the need for co-funding is a significant and recognised barrier for SMEs.</li> </ul>	

<b>PRIORITY WHEN AWARDING GRANTS</b>	
<p>Current <i>example</i> of the application of the measure:</p> <ul style="list-style-type: none"> <li>§ In the ECO-Innovation programme SMEs are prioritized when grants are awarded.</li> </ul>	
<p><i>Advantages:</i></p> <ul style="list-style-type: none"> <li>§ Can serve as an incentive for SMEs to participate.</li> <li>§ Increases SME participation in programme.</li> </ul>	<p><i>Disadvantages:</i></p> <ul style="list-style-type: none"> <li>§ Good projects may be discarded because they originate from large companies.</li> </ul>
<p><i>Circumstance</i> where the measure is likely to be <i>most effective</i>:</p> <ul style="list-style-type: none"> <li>§ Can be applied for most programmes if relevant and accepted.</li> </ul>	

## ANNEX 1: RESULTS OF REVIEW OF 83 PIECES OF EU LEGISLATION WITH SME MEASURES

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Council Directive 2003/96/EC</b> of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity	Taxation	reduce distortions of competition resulting from different VAT rates; introduce tax incentives for energy savings and activities reducing emissions; differences in the national levels of energy taxation	Information costs (companies need to know the various rates they can apply); administrative costs (companies may need to apply for exemptions or reduced rates); internal costs (companies need to readjust their internal accounting systems with the new rates)	Size related exemption	small producers of electricity exempted provided that they tax the energy products used for the production of that electricity.
<b>Council Directive 2006/112/EC</b> of 28 November 2006 on the common system of value added tax (VAT Directive)	Taxation	correct discrepancies in VAT rules	Information costs (companies need to know the various rates they can apply); administrative costs (companies may need to apply for exemptions or reduced rates); internal costs (companies need to readjust their internal accounting systems with the new rates)	Special treatment	Member States are allowed to implement simplified VAT charging and collection schemes for small enterprises (not defined), such as flat-rate VAT schemes
				Size related exemption	Member States are permitted to make use of exemptions and graduated tax relief systems, though the Directive sets annual turnover thresholds above which such systems cannot be applied. These ceilings vary between Member States, but are generally very low (up to a maximum of €10,000 in many cases), so would be likely to apply to only the very smallest businesses.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Council Directive 72/221/EEC</b> of 6 June 1972 concerning coordinated annual surveys of industrial activity	Statistics	Statistics on the structure, importance and development of industry and small craft industries in Member States is inadequate or insufficiently comparable to serve as a reliable basis for the work of the Commission	Provide annual statistics on the structure and productive activity of the company (number of employees, wages, turnover, sales, production, purchasing etc.)	Size related exemption	The (yearly) surveys shall cover all industrial undertakings and small businesses, if any, which employ twenty or more persons. Surveys shall, at least once in every five years, be extended to cover undertakings employing fewer than 20 persons. Data to be collected on undertakings employing from twenty to ninety-nine persons shall, however, cover only the variables concerning the number of persons employed, turnover, gross wages and salaries paid, and also purchases of raw materials, intermediate products and industrial services. Data to be collected on undertakings employing from twenty to ninety-nine persons shall cover only the variables concerning the number of persons employed, turnover, gross wages and salaries paid, and also purchases of raw materials, intermediate products and industrial services.
<b>Regulation (EC) No 177/2008</b> of the European Parliament and of the Council of 20 February 2008 establishing a common framework for business registers for statistical purposes and repealing <b>Council Regulation (EEC) No 2186/93</b>	Statistics	Statistics in the Community is not comparable enough, business registers are different across Member States, statistical surveys are not coordinated, much of the data requested already exists in administrative and legal files	Provide the national authorities with the data necessary to include in the business register.	Only a reference to SMEs	Business registers are one method by which to reconcile the conflicting requirements for collating increased information on enterprises on the one hand and lightening their administrative burden on the other, in particular by using existing information in administrative and legal files, especially in the case of micro, small- and medium-sized enterprises

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Regulation (EC) No 638/2004</b> of the European Parliament and of the Council of 31 March 2004 on Community statistics relating to the trading of goods between Member States and repealing <b>Council Regulation (EEC) No 3330/91</b>	Statistics	Wording of rules on compiling statistics relating to the trading of goods between Member States are not sufficiently easy to understand for companies and national services providing the data, nor for users	Monthly provision of information on commodity, trading partner, value and quantity of goods, nature of transaction	Size related exemption	Member States shall define each year thresholds expressed in annual values of intra-Community trade, below which parties are exempted from providing any Intrastat information or may provide simplified information. Member States may define other thresholds below which parties may benefit from the following simplification: exemption from providing information about the quantity of the goods; exemption from providing information about the nature of the transaction; possibility of reporting a maximum of 10 of the detailed relevant subheadings of the Combined Nomenclature, that are the most used in terms of value, and regrouping the other products.
<b>Regulation (EC) No 450/2003</b> of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index	Statistics	Lack of regular labour cost indices and short term labour cost statistics on Community level.	To provide information on labour costs on a quarterly basis	Only a reference to SMEs	The benefits of collecting, at Community level, complete data on all segments of the economy should be balanced against the reporting possibilities and the response burden on small and medium-sized enterprises

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Council Regulation (EC) No 530/1999</b> of 9 March 1999 concerning structural statistics on earnings and on labour costs	Statistics	There is no comparable data on labour costs and structure and distribution of earnings collected in a harmonized, regular fashion	Respond to a survey every four years on labour costs, number of employees and number of hours worked as well as demographics, length of service and type of contract for each employee.	Only a reference to SMEs	*Although the importance of complete data of all segments of the economy should be fully recognised, it should be carefully weighed against the reporting possibilities and the response burden in specific areas, in particular in relation to small and medium-sized enterprises (SMEs). *Surveys shall be carried out through the appropriate national authorities, which shall draw up the appropriate methods for collecting the information, taking into account the response burdens, notably on SMEs. *In order to reduce the burden on enterprises, particularly on SMEs, surveys need not be carried out if the national authorities have information from other appropriate sources. *The Commission shall...compile a report taking into account the results of pilot studies, in particular, on the basis of existing sources in the area of statistical units with less than ten employees. The report shall assess the application of the provisions of this Regulation relating to units with less than ten employees.
<b>Council Regulation (EC) No 1165/98</b> of 19 May 1998 concerning short-term statistics	Statistics	Statistics currently collected have not been able to take account of economic and technical changes, are inadequate, not reliable enough or comparable across Member States.	Provide data on less than yearly basis (e.g. monthly, quarterly...) on their turnover, staff, output, material costs, purchasing, orders, prices, hours worked labour costs etc.	Simplification and/or coordination of regulatory requirements	To consider simplification in order to benefit SMEs, including the use of electronic means to collect statistical information
<b>Regulation (EC) No 295/2008</b> of the European Parliament and of the Council of 11 March 2008 concerning structural business statistics (recast) (Text with EEA relevance)	Statistics	Previous regulation (58/97) has been amended several times and was not clear enough, new requirements have arisen from new Community policy initiatives (need for data on services, business demography and for a more flexible tool)	Provide the national authorities with the requested data (frequency and type of data varies, but not with company size)	Only a reference to SMEs	Quality evaluation shall be carried out comparing the benefits of the availability of the data with the costs of collection and the burden on business, especially on small enterprises.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Regulation (EC) No 2150/2002</b> of the European Parliament and of the Council of 25 November 2002 on waste statistics	Statistics	Regular, comparable Community statistics on the production and management of waste from businesses and private households are required by the Community for monitoring the implementation of waste policy	Provide the national authorities with data on generation and recovery/disposal of waste bi-annually	Size related exemption	In order to reduce the administrative burden on small enterprises, enterprises of less than 10 employees shall be excluded from surveys, unless they contribute significantly to the generation of waste
<b>Directive 2006/25/EC</b> of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	Optical radiation has adverse effects on the health and safety of workers, in particular damage to the eyes and to the skin. In order to avoid possible distortions of competition, minimum protection levels are needed.	The employer...shall assess and, if necessary, measure and/or calculate the levels of exposure to optical radiation to which workers are likely to be exposed. The assessment, measurement and/or calculations referred to in paragraph 1 shall be planned and carried out by competent services or persons at suitable intervals. The data obtained from the assessment...shall be preserved in a suitable form so as to permit their consultation at a later stage. Risk assessment shall be updated on a regular basis. The employer shall... devise and implement an action plan comprising technical and/or organisational measures designed to prevent the exposure exceeding the limit values. The employer shall... ensure that workers who are exposed to risks from artificial optical radiation at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment	Tailor made information, coaching, training	The Commission should draw up a practical guide to help employers, in particular managers of SMEs, better to understand the technical provisions of this Directive.
<b>Directive 2004/40/EC</b> of the European Parliament and of the Council of 29 April 2004 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (18th individual Directive within the meaning of Article 16(1)	Occupational health and safety	Electromagnetic fields have known short-term adverse effects on the human body. In order to avoid possible distortions of competition, minimum protection levels are needed.	The employer...shall assess and, if necessary, measure and/or calculate the levels of electromagnetic fields to which workers are exposed. The assessment, measurement and/or calculations referred to in paragraph 1 shall be planned and carried out by competent services or persons at suitable intervals. The data obtained from the assessment...shall be preserved in a suitable form so as to permit their consultation at a later stage. Risk assessment shall be updated on a regular basis. The employer shall... devise and implement an action plan comprising technical and/or organisational measures designed to	Only a reference to SMEs	Directives adopted to improve working environment are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
of <b>Directive 89/391/EEC</b> )			prevent the exposure to exceed the limit values. The employer shall... ensure that workers who are exposed to risks from electromagnetic fields at work and/or their representatives receive any necessary information and training relating to the outcome of the risk assessment. Appropriate health surveillance shall be carried out, the employer shall ensure that the doctor and/or the medical authority responsible for the health surveillance has access to the results of the risk assessment, results of health surveillance shall be preserved.		
<b>Directive 2003/18/EC</b> of the European Parliament and of the Council of 27 March 2003 amending Council <b>Directive 83/477/EEC</b> on the protection of workers from the risks related to exposure to asbestos at work (Text with EEA relevance)	Occupational health and safety	Those who are now most at risk, in particular workers who remove asbestos and workers who accidentally come across asbestos at work in the course of servicing and maintenance activities, were not sufficiently covered by directive 83/477; sea and air sectors had derogations from that directive and thus not all workers were protected; there is new research on the limits of exposure, new technology on measuring the risks and new work situations not taken into account.	Notification (of activities during which workers are or may be exposed to dust containing asbestos) shall be submitted by the employer to the responsible authority of the Member States, before the work commences, in accordance with national laws, regulations and administrative provisions. Each time a change in working conditions is likely to result in a significant increase in exposure to dust from asbestos or materials containing asbestos, a new notification must be submitted. The exposure of workers to dust arising from asbestos or materials containing asbestos at the place of work must be reduced to a minimum through the introduction of a number of safety measures. Measurement of asbestos fibres in the air at the workplace shall be carried out regularly. Employers shall ensure that no worker is exposed to an airborne concentration of asbestos in excess of 0,1 fibres per cm <sup>3</sup> as an eight-hour time-weighted average. Before beginning demolition or maintenance work, employers shall take, if appropriate by obtaining information from the owners of the premises, all necessary steps to identify presumed asbestos-containing materials. Employers shall provide appropriate training for all workers who are, or are likely to be, exposed to asbestos-containing dust. Such training must be provided at regular intervals and at no cost to the workers. Before carrying out asbestos demolition or removal work, firms must provide evidence of	Only a reference to SMEs	These amendments are limited to the minimum in order not to impose an unnecessary burden on the creation and development of small and medium-sized enterprises.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
			their ability in this field.		
<b>Directive 2003/10/EC</b> of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	Exposure to noise may have adverse effects on the health and safety of workers, in particular damage to hearing. In order to avoid possible distortions of competition, minimum protection levels are needed.	The employer...shall assess and, if necessary, measure the levels of noise to which workers are exposed. The methods and apparatus used shall be adapted to the prevailing conditions. The assessment, measurement and/or calculations shall be planned and carried out by competent services or persons at suitable intervals. The data obtained from the assessment...shall be preserved in a suitable form so as to permit their consultation at a later stage. Risk assessment shall be updated on a regular basis. The employer shall... devise and implement an action plan comprising technical and/or organisational measures designed to prevent the exposure to exceed the limit values. Appropriate, properly fitting individual hearing protectors shall be made available to workers. The employer shall... ensure that workers who are exposed to risks from noise at work and/or their representatives receive any necessary information and training relating to the risks. Appropriate health surveillance shall be carried out, results of health surveillance shall be preserved.	Only a reference to SMEs	Directives adopted to improve working environment are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.
<b>Directive 2002/44/EC</b> of the European Parliament and of the Council of 25 June 2002 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration) (sixteenth individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	Vibration have adverse effects on the on the health and safety of workers, in particular muscular/bone structure, neurological and vascular disorders.	The employer...shall assess and, if necessary, measure the levels of mechanical vibration to which workers are exposed. The assessment, measurement and/or calculations shall be planned and carried out by competent services or persons at suitable intervals. The data obtained from the assessment...shall be preserved in a suitable form so as to permit their consultation at a later stage. Risk assessment shall be updated on a regular basis. The employer shall... devise and implement an action plan comprising technical and/or organisational measures designed to prevent the exposure to exceeded limit values. The employer shall... ensure that workers who are exposed to risks from mechanical vibration at work and/or their	Only a reference to SMEs	Directives adopted to improve working environment are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
			representatives receive any necessary information and training relating to the risks. Appropriate health surveillance shall be carried out, results of health surveillance shall be preserved.		
<b>Directive 2001/45/EC</b> of the European Parliament and of the Council of 27 June 2001 amending <b>Council Directive 89/655/EEC</b> concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	Improvement of occupational safety, hygiene and health is an objective which may not be subordinated to purely economic considerations. Ladders, scaffolding and ropes are the equipment most commonly used in performing temporary work at a height and the safety and health of workers engaged in this type of work therefore depend to a significant extent on their correct use	Any employer who intends to have temporary work carried out at a height must select equipment affording adequate protection against the risks of falls from a height. Detailed provisions for mounting, dismounting, use and storage of scaffolding and ladders.	Temporal Exemption	Member States were allowed to make use of a transitional period of 2 years (till July 2006) in order to enable SMEs to adapt
<b>Directive 1999/92/EC</b> of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	decrease risks associated to dangerous work environments	the employer shall take technical and/or organisational measures (prevention measures); the employer shall assess the risk arising from explosive atmospheres (risk assessment); employer must classify places where explosive atmospheres may occur; employers shall ensure a safe working environment; companies shall set up adequate supervision of working environment; firms draft a "explosion protection document"	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 1999/38/EC</b> of 29 April 1999 amending for the second time <b>Directive 90/394/EEC</b> on the protection of workers from the risks related to exposure to carcinogens	Occupational health and safety	protect workers from carcinogens and cell mutagens risks	Companies should assess the risk; monitor and keep relevant documents; ensure the working environment is as safe as possible by taking technical measures	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
at work and extending it to mutagens					
<b>Council Directive 98/24/EC</b> of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	protect workers from risks arising from the effects of chemical agents that are present at the workplace or as a result of activities involving chemical agents	The employer must 1) Determine the presence of hazardous chemical agents; 2) Assess risks by looking at a minimum set of criteria; 3) risk assessment document & update it 4) assess risk of new activities and take preventive measures before commencing it 5) ensure that the risk is eliminated or reduced to a minimum 6) set up "action plans" (to be implemented in the event of an accident) 7) make available to employees and their representatives information on emergency arrangement, the results of the risk assessment and adequate training 8) ensure workers and/or their representatives are consulted	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 97/42/EC</b> of 27 June 1997 amending for the first time <b>Directive 90/394/EEC</b> on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	tackle working environments with carcinogen risks	companies must assess the exposure of workers; reduce or replace the use of these substances; ensure hygiene and individual protection; draft an assessment, update it a; and make it available to authorities upon request; in emergency situations, ensure safety and inform workers; ensure Information and training of workers; record keeping of workers' health condition for at least 40 years after the end of exposure; ensures the consultation and participation of workers	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 92/104/EEC</b> of 3 December 1992 on the minimum requirements for improving the safety and health protection of workers in surface and underground mineral-extracting industries (twelfth individual Directive within the meaning of Article 16 (1) of <b>Directive</b>	Occupational health and safety	fills the legal vacuum arising from the exclusion of the extractive industries in previous directives	Employers shall ensure 1) safety and health of workers (organisational measures, prevention, training, emergency situations); 2) adequate supervision during activities; 3) provide workers with information; 4) ensure regular health checks for workers; 5) favour consultation and participation of workers 5) draw up a health and safety document prior to activity and update it regularly	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
89/391/EEC)					
<b>Council Directive 92/91/EEC</b> of 3 November 1992 concerning the minimum requirements for improving the safety and health protection of workers in the mineral-extracting industries through drilling (eleventh individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	tackle risky working environment in mineral-extracting industries through drilling	Employers shall ensure 1) safety and health of workers (organisational measures, prevention, training, emergency situations); 2) adequate supervision during activities; 3) provide workers with information; 4) ensure regular health checks for workers; 5) favour consultation and participation of workers 6) draw up a health and safety document prior to activity and update it regularly 7) report any serious accident	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 92/85/EEC</b> of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	prevent these workers from being exposed to risky activities	employers should assess activities involving a risk; make necessary adjustments; inform workers and their representatives of the assessment;	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.

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<b>Council Directive 92/58/EEC</b> of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	mark some hazards, which are currently not appropriately marked	Employers shall provide safety and/or health signs where hazards cannot be avoided or adequately reduced by preventive measures; employers shall inform and instruct workers and/or their representatives of the measures taken; workers must be consulted and allowed to participate on this issue	Size related exemption	Member States may specify categories of undertakings (by size or activity) allowed to replace totally, partially or temporarily the illuminated signs, and/or acoustic signals with other means (but with the same level of protection).
<b>Council Directive 92/57/EEC</b> of 24 June 1992 on the implementation of minimum safety and health requirements at temporary or mobile construction sites (eighth individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	tackle the risks and occupational accidents associated with temporary or mobile construction sites	companies shall appoint one or more coordinators for safety and health matters; companies shall draw a safety and health plan prior to the setting up of a construction site; companies shall display the prior notice on the construction site and update it; the company coordinator shall monitor safety measures; companies shall inform and consult workers and allow their participation	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 91/383/EEC</b> of 25 June 1991 supplementing the measures to encourage improvements in the safety and health at work of workers with a fixed- duration employment relationship or a temporary employment relationship	Occupational health and safety	fixed-duration/temporary employees may be more exposed to the risk of occupational accidents and diseases	companies shall inform employees of any risks before prior to commencing work; companies shall provide details of the occupational qualifications features of the job to the temporary employment business; companies shall provide adequate training	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Council Directive 90/679/EEC</b> of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	adequately protect certain categories of workers	Employers shall replace whenever possible dangerous biological agents; employers shall prevent exposure to risks and reduce them; employers shall inform the competent authority in certain cases; employers shall ensure hygiene and individual protection; information and training of workers; more specific information for workers in particular cases; employers shall keep a list of workers exposed to group 3 and/or 4 agents; list is to be kept for at least 10 years after the end of exposure or for up to 40 years after the last known exposure; consultation and participation of workers; notification to the competent authority prior to the first use of group 2, 3 and 4 biological agents; employers shall ensure health surveillance of workers subjected to risks; individual medical records are kept for at least 10 years after the end of exposure or for up to 40 years in certain cases; further obligations for health and veterinary care facilities	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 90/270/EEC</b> of 29 May 1990 on the minimum safety and health requirements for work with display screen equipment (fifth individual Directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	adapt safety measures to workplaces using new technologies	Employers are obliged to 1) analyse workstations 2) evaluate the safety and health conditions 3) remedy any risks to eyesight, physical problems and problems of mental stress; employers have to plan work in such a way as to avoid prolonged exposure to workstations; companies shall inform, train and consult workers	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 90/269/EEC</b> of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of	Occupational health and safety	avoid risky situations when workers handle heavy loads	companies shall avoid manual handling of heavy loads by workers; ensure adequate protection when manual handling is necessary; workers shall receive information on the weight of loads and gravity features; employers shall train workers on handling loads; enable consultation and participation of workers	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.

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Article 16 (1) of <b>Directive 89/391/EEC</b> )					
<b>Council Directive 89/656/EEC</b> of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	avoid exposing workers to risky work conditions	employer shall provide free personal protective equipment in keeping the Community safety and health protection provisions; employers shall assess the conditions of use of personal protective equipment; workers will be provided with adequate information and training on the protective material; employers shall assess protective material prior to use; workers shall be consulted and shall participate	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 89/654/EEC</b> of 30 November 1989 concerning the minimum safety and health requirements for the workplace (first individual directive within the meaning of Article 16 (1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	protect workers against risky working conditions	workers shall participate and be consulted; : workplaces which are used for the first time after 31/12/1992 have to comply, whilst workplaces already in use before 1 January 1993 must comply with the requirements at the latest three years after 31/12/1992 (this is a temporal exemption); companies shall ensure safety equipment, devices and routes are maintained; maintain the workplace to adequate level of hygiene;	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints that would hold back the creation and development of SMEs.
<b>Council Directive 89/391/EEC</b> of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work	Occupational health and safety	protect workers against risky working conditions	Employers shall ensure the safety and health of workers; assess the occupational risks; to keep a list of/reports on occupational accidents; take necessary measures for in emergency situations; inform, train and consult workers	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints; Member States shall define, in the light of the nature of the activities and size of the undertakings, the obligations to be met by the different categories of undertakings

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<b>Directive 2007/65/EC</b> of the European Parliament and of the Council of 11 December 2007 amending Council <b>Directive 89/552/EEC</b> on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities	Internal market	A need for a standard set of rules governing the audiovisual media services industry so as to remove barriers to cross-border trade (service provision).	Various content/ editorial requirements (product placement, public interest issues). Also a requirement to provide basic information to the authorities(contact details). Some additional non-requirements (but can Member States make them requirements?) around provision of services for the hearing impaired etc.	Only a reference to SMEs	Measures were to promote a single market, but bearing in mind the needs of SMEs
<b>Council Directive 70/156/EEC</b> of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers	Internal market	A lack of a harmonised system of testing and authorising automobiles	companies must get type approval for automobiles and components, as set out in a number of Directives. To get type approval companies must provide extensive information to their approval body(ies) in their Member States. May include prototypes for destructive testing	Size related exemption	the exemption is not specifically for SMEs, but is for automobiles manufactured in "small" quantities (e.g. 500 cars placed on the market in a year, varies depending on type of automobile). In these cases manufactures can apply to their approval body to have reduced requirements, though other MS must agree to this. If granted then manufacturers are allowed to be exempt to varying degrees, though details are not set out in the Directive and is at the discretion of the MS approval body. Actual application is unknown.
<b>Directive 2007/45/EC</b> Of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for prepacked products, repealing <b>Council Directives 75/106/EEC</b> and <b>80/232/EEC</b> , and amending <b>Council Directive 76/211/EEC</b>	Internal market	Member States were able to set by law quantities for prepacked products, meaning that businesses could not respond to consumer demand	None	Temporal Exemption	In some sectors (milk, coffee, pasta and butter) rules may be left in place until 2012

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<b>Directive 2006/123/EC</b> of the European Parliament and of the Council of 12 December 2006 on services in the internal market	Internal market	A lack of progress with the SM in services (compared to goods). Implicitly a factor in this was seen to be legal/ administrative complexities of providing services outside of businesses' country of origin, and particularly variations in legal/ admin systems and difficulties businesses face in finding out about these systems.	The Directive primarily imposes requirements on Member States. Various measures simplifying admin/ legal procedures such as a single national contact point for procedures (e.g. registration with a professional body, addition to a register). The Single contact point provides information on all requirements in that country. No requirement though to provide information in all languages. Communication with contact point, and any legal procedures must be easy, possible electronically, and possible at a distance.	Simplification and/or coordination of regulatory requirements	Nothing specific to SMEs as these are for use by all businesses
<b>Directive 2004/18/EC</b> of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts	Internal market	Variations in public procurement procedures between Member States making it hard for businesses to take advantage of opportunities outside of their country, and also a lack of transparency making it hard to identify and act on cases of discrimination.	Obligations are primarily imposed on public authorities in the Member States. Member States are required to follow set procedures for contracts over the thresholds. These cover the selection criteria used, the notification procedure used, procedures for notifying winners/ losers, the treatment of electronic tenders etc.	Only a reference to SMEs	Member States 'advised' to include provisions regarding sub-contracting in public procurement procedures in order to increase the involvement of SMEs
<b>Directive 2004/17/EC</b> of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors	Internal market	Variations in public procurement procedures between Member States making it hard for businesses to take advantage of opportunities outside of their country, and also a lack of transparency making it hard to identify and act on cases of discrimination.	Obligations are primarily imposed on public authorities in the Member States. Member States are required to follow set procedures for contracts over the thresholds. These cover the selection criteria used, the notification procedure used, procedures for notifying winners/ losers, the treatment of electronic tenders etc.	Only a reference to SMEs	Member States 'advised' to include provisions regarding sub-contracting in public procurement procedures in order to increase the involvement of SMEs
<b>Directive 98/8/EC</b> of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market	Internal market	Lack of recognition between Member States of authorisations and permissions granted to products, leading to expensive re-testing and re-authorising each time a	For every product companies must obtain authorisation from the competent authority in the Member State where they are based. To get authorisation businesses generally have to provide a dossier on the product and its active ingredients which shows chemical composition, safety information, proof of testing etc. The legislation	Only a reference to SMEs	Member States are required to ensure that administrative burdens for SMEs are not too onerous, but there are no specifics

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		company wishes to sell a product in another country. Also by implication variations in the level of safety resulting from product tests and authorisations	also includes labelling requirements		
<b>Directive 97/23/EC</b> of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment	Internal market	lack of recognition between Member States regarding the testing and authorisation of pressure equipment leading to expensive re-testing and re-authorising each time a company wishes to sell a product in another country.	In order to place a product on the market, businesses must obtain a CE marking. To get the CE marking products must be externally tested by a Notified Body, after which no Member State can prohibit the sale of the product. Notified Bodies charge for the service at a market rate.	Only a reference to SMEs	The text of the Directive is simply required to be clear to SMEs (mainly concerning technical information about testing requirements).
<b>Regulation (EC) No 1370/2007</b> of the European Parliament and of the Council of 23 October 2007 on public passenger transport services by rail and by road and repealing <b>Council Regulations (EEC) Nos 1191/69 and 1107/70</b>	Internal market	A lack of competition in the provision of public transport services by rail and road.	None - obligation to open to tender is placed on Member States	Size related exemption	Where contracts are awarded to SMEs (operating a fleet of less than 23 vehicles), the thresholds above which the contract must be opened to competitive tender are doubled.
<b>Council Regulation (EC) No 6/2002</b> of 12 December 2001 on Community designs	Internal market	A need to protect designs and reduce counterfeiting, in order to stimulate innovation and product development	The Regulation establishes a procedure through which businesses may register a design with the Office for Harmonisation in the Internal Market. The design is then protected from copying for between 5-25 years. There is a standard fee per application. registration requirements are kept to a minimum - there is no need to submit detailed designs. Challenges can be made as a result of which designs are subject to more investigation	Only a reference to SMEs	The Regulation was explicit about the need to impose a minimum cost on businesses, and on SMEs in particular. But there are no reduced fees for SMEs.
<b>Regulation (EC) No 1592/2002</b> of the European Parliament	Internal market	Variations in technical standards applied to aircraft safety between	Costs of compliance (meeting technical specifications), plus costs of applying for certificates	Only a reference to SMEs	Text indicates that the fees should take into account the ability of small undertakings to pay. However there are no exemptions or reduced

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and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency		Member States			fees in operation.
<b>Regulation (EC) No 1901/2006</b> of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending <b>Regulation (EEC) No 1768/92</b> , <b>Directive 2001/20/EC</b> , <b>Directive 2001/83/EC</b> and <b>Regulation (EC) No 726/2004</b>	Internal market	Medicinal products tend not to be tested specifically for use with children. There is a market failure since industry cannot generate profits working with children, and is thus less inclined to invest in this area	According to the legislation the key area for SMEs is in respect of the Paediatric Use Marketing Authorisation (PUMA) form. The PUMA is applicable to existing medicine where the patent has expired, giving firms the right to remarket the product for children with exclusivity rights for 10 years.	Simplification and/or coordination of regulatory requirements	The Regulation is explicit about the need to get SMEs involved in the R&D process. For this reason, application arrangements have been simplified. Businesses can use existing information held on the use of a product with children to apply for a PUMA, giving them the right to market the product for children. Thus avoiding the need to go through a complicated retesting process, a major barrier for SMEs
<b>Regulation (EC) No 726/2004</b> of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Internal market	a lack of mutual recognition of authorisations of medicinal products between Member States, and a need for a centralised system of authorisations for new high-tech products	All medicinal products need authorisation. Certain medicinal products (derived from biotechnology, orphan medicines, or medicines designed to treat certain ailments e.g. AIDS) must receive authorisation through the centralised procedure (i.e. From the EMA), for others it is optional (and may instead be from national CAs). Authorisation is based on the requirements set out in Directive 2001/83/EC (e.g. clinical trial data etc). There is also an inspection of facilities to ensure compliance. Fees are set by the Commission - and there is an allowance for SMEs	Special treatment	reduced fees - see Regulation 2049/2005
				Special treatment	Payment is waived if Agency advice has been given and the application is unsuccessful, 90% reduction in fees for inspections, payment for authorisation/ inspection procedures is deferred until the final decision is made on the authorisation
<b>Commission Regulation (EC) No 2049/2005</b> of 15 December 2005 laying down, pursuant to <b>Regulation (EC) No 726/2004</b> of the European Parliament and of the Council, rules regarding the payment	Internal market	a lack of mutual recognition of authorisations of medicinal products between Member States, and a need for a centralised system of authorisations for new high-tech products	Fees associated with the operation of Regulation (EC) No 726/2004	Tailor made information, coaching, training	free dedicated SME assistance service within the EMA with user guides

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of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises					
<b>Directive 2006/46/EC</b> of the European Parliament and of the Council of 14 June 2006 amending Council <b>Directives 78/660/EEC</b> on the annual accounts of certain types of companies, <b>83/349/EEC</b> on consolidated accounts, <b>86/635/EEC</b> on the annual accounts and consolidated accounts of banks and other financial institutions and <b>91/674/EEC</b> on the annual accounts and consolidated accounts of insurance undertakings	Internal market	The requirements for financial statements in the EU were not fully consistent	Companies are obliged to disclose in their financial accounts transactions with related parties, including the amount of such transactions, the nature of the related party relationship and other information about the transactions necessary for an understanding of the financial position of the company, if such transactions are material and have not been concluded under normal market conditions. They are also required to report off-balance sheet transactions.	Size related exemption	Member States may exempt small companies from the requirements concerning related parties and off-balance-sheet arrangements.
<b>Directive 2006/48/EC</b> of the European Parliament and of the Council of 14 June 2006 relating to the taking up and pursuit of the business of credit institutions	Internal market	a lack of consistency in the way in which Member States authorise and supervise credit institutions (banks etc).	the Directive set specific financial criteria that credit institutions must meet and maintain, under supervision from competent authorities.	Special treatment	smaller credit institutions may opt for a more suitable risk assessment procedure, reflecting the nature of their operations

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<b>Directive 2005/32/EC</b> of the European Parliament and of the Council of 6 July 2005 establishing a framework for the setting of ecodesign requirements for energy-using products and amending <b>Council Directive 92/42/EEC</b> and <b>Directives 96/57/EC</b> and <b>2000/55/EC</b> of the European Parliament and of the Council	Internal market	disparities between the laws or administrative measures adopted by the Member States in relation to the ecodesign of energy-using products can create barriers to trade and distort competition in the Community and may thus have a direct impact on the establishment and functioning of the internal market	meet min standard for energy use. Certification and reporting.	Only a reference to SMEs	Member States to consider ways of encouraging SMEs to integrate ecodesign
<b>Regulation (EC) No 715/2007</b> of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information	Internal market	variation in the technical requirements for emissions standards for approval of motor vehicles across Member States could reduce environmental protection.	Manufacturers shall 1) demonstrate that all replacement parts and new vehicles sold in the Community meet approval standards 2) ensure that type approval procedures for verifying conformity of pollution control devices and in-service conformity are met 3) ensure that the tailpipe and evaporative emissions are effectively limited throughout the normal life of the vehicles under normal conditions of use. 4) equip vehicles so that the components likely to affect emissions are designed, constructed and assembled so as to enable the vehicle, in normal use, to comply with this Regulation and its implementing measures.	Simplification and/or coordination of regulatory requirements	manufacturers are required to make available technical information to ensure that SMEs are not excluded from maintenance, but this is not solely for the benefit of SMEs

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<b>Regulation (EC) No 1394/2007</b> of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending <b>Directive 2001/83/EC</b> and <b>Regulation (EC) No 726/2004</b>	Internal market	variations in procedures for authorisation between Member States, plus a need to increase research in this area	Specific requirements for marketing authorisation (donation, procurement and testing of human cells; clinical trials; etc.). Obligation to notify consumers of product characteristics, labelling and packaging requirements, requirements for the leaflet. Post-authorisation follow-up and risk management obligations.	Special treatment	in addition to the standard fee reduction for SMEs available from the European Medicines Agency, SMEs are eligible for a 50% fee reduction in marketing authorisation where there is proof that the product has a particular public interest. For SMEs carrying out studies to demonstrate quality and non-clinical safety of products, a system of evaluation and certification is introduced whereby the European Medicines Agency can carry out these evaluations independently of any marketing authorisation
<b>Regulation (EC) No 1411/2000</b> of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products	Internal market	Research of orphan medicinal products is not likely to be offset by sufficient revenues without public support.	Orphan medicinal products are subject to the centralised authorisation procedure (i.e. They must be approved by the European Medicines Agency). Once approved medicines are granted exclusive marketing rights for 10 years, in order to stimulate investment	Simplification and/or coordination of regulatory requirements	Procedures for orphan medicinal products have been simplified and incentives (longer exclusivity rights) introduced in order to stimulate investment
European Parliament and <b>Council Directive 94/62/EC</b> of 20 December 1994 on packaging and packaging waste	Environmental protection	high level of environmental damage resulting from disposal of packaging materials	Registration, recording and reporting data on packaging waste to competent authorities, payment for fulfilling recycling obligation.	Only a reference to SMEs	Member States should take account of the ability of SMEs to provide the data needed to maintain the information systems
<b>Directive 2006/66/EC</b> of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Text with EEA relevance)	Environmental protection	need for collection schemes so that end-users can discard all waste portable batteries and accumulators conveniently and free of charge	Producers should finance the costs of collecting, treating and recycling all collected batteries and accumulators minus the profit made by selling the materials recovered	Size related exemption	option of exemption from financial contribution to waste treatment and recycling requirements
<b>Council Directive 1999/13/EC</b> of 11 March 1999 on the limitation of	Environmental protection	public health and the environment were being damaged by particularly	not to exceed accepted levels of VOC emissions	Special treatment	standards applied are higher for new installations; SMEs are permitted to use a more flexible definition of what constitutes an existing

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emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations		harmful emissions from the use of organic solvents			installation
<b>Directive 2000/53/EC</b> of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles	Environmental protection	between 8 and 9 million tonnes of waste is generated annually within EU by end of life vehicles	licensing, reporting and recording. Recycling obligation on scrap dealers?	Only a reference to SMEs	provisions should not make the collection, dismantling, treatment and recycling market uncompetitive for SMEs
<b>Directive 2002/51/EC</b> of the European Parliament and of the Council of 19 July 2002 on the reduction of the level of pollutant emissions from two- and three-wheel motor vehicles and amending <b>Directive 97/24/EC</b>	Environmental protection		ensure products sold have certificates or meet standards	Only a reference to SMEs	decisions regarding emissions targets should take account of the effect on small producers
<b>Directive 2005/64/EC</b> of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending <b>Council Directive 70/156/EEC</b>	Environmental protection	minimizing the environmental impact of end of life vehicles by requiring that vehicles be designed from the conception phase with a view to facilitating reuse, an not be sufficiently achieved by the Member States acting alone	1) comply with regulations to get 'Certificate of Compliance' 2) ensure that the materials used for the construction of a vehicle type comply with the provisions of Article 4(2)(a) of Directive 2000/53/E 3)the manufacturer shall recommend a strategy to ensure dismantling, reuse of component parts, recycling and recovery of materials	Size related exemption	small producers are excluded from the Directive since the environmental impact is considered relatively small
<b>Directive 2006/32/EC</b> of the European Parliament and of the Council of 5 April 2006 on energy end-use efficiency and energy services and repealing <b>Council Directive 93/76/EEC</b>	Environmental protection	need for improved energy end-use efficiency and promote the production of renewable energy, as building of new capacity or improvement of transmission and distribution are long term	energy distributors/retail energy sales companies are required to provide information to Member States regarding customer energy consumption, efficiency etc, and to provide customers with information regarding prices, efficiency etc.	Size related exemption	small distributors and retailers of energy are exempt from certain reporting requirements, and from providing customers with detailed pricing information, and meters

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<b>Regulation (EC) No 1907/2006</b> of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending <b>Directive 1999/45/EC</b> and repealing <b>Council Regulation (EEC) No 793/93</b> and <b>Commission Regulation (EC) No 1488/94</b> as well as <b>Council Directive 76/769/EEC</b> and <b>Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC</b> and <b>2000/21/EC</b>	Environmental protection	Review of Council Directives 67/548/EEC , 76/769/EEC, 1999/45/EC and Council Regulation (EEC) No 793/93 found a need to promote the development of alternative methods for the assessment of hazards of substances to eliminate disparities between the laws, regulations and administrative provisions in governing Chemicals in Member States directly affecting protection public health and the environment	1)industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected 2) Info should be systematically conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment 3) register company and remain compliant with regulations	Tailor made information, coaching, training	Member States must establish national helpdesks in order to provide businesses with advice and support with implementation; this service is expected to benefit SMEs particularly
				Special treatment	SMEs will benefit from reduced fees when registering substances with the European Chemicals Agency
<b>Regulation (EC) No 761/2001</b> of the European parliament and of the council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)	Environmental protection	Need to promote continual improvements in the environmental performance of organisations by establishing and implementing environmental management systems by organisations	1) Environmental management standards and reporting, 2)apply to accreditation board and pass standards 3)used logo in their correspondence/publications, 4)performed Internal audits of environmental standards	Tailor made information, coaching, training	MS shall: facilitate access to information, support funds, public institutions and public procurement; establish or promote technical assistance measures, especially in conjunction with initiatives from appropriate professional or local points of contact (e.g. local authorities, chambers of commerce, trade or craft associations; ensuring that reasonable registration fees encourage higher participation.
				Size related exemption	Reduced reporting requirements - SMEs may not be required to report on an annual basis in order to be registered for EMAS

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<b>Regulation (EC) No 2037/2000</b> of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer	Environmental protection	Increased UV-B radiation resulting from ozone depletion poses a significant threat to health and environment. Therefore need for further efficient measures to be taken in order to protect human health and the environment continued emissions of against adverse effects resulting from ozone depleting substances .	1)ensure products are CFC free or meet standards 2)obtain import/export licence to release for free circulation, any product on the controlled substances list 3) dispose of controlled/ banned substances appropriately	Only a reference to SMEs	Member States should consider providing appropriate forms of assistance specifically to enable SMEs to adapt to the new requirements
<b>Council Directive 94/45/EC</b> of 22 September 1994 on the establishment of a European Works Council or a procedure in Community-scale undertakings and Community-scale groups of undertakings for the purposes of informing and consulting employees	Employment conditions	Procedures for informing and consulting employees in the Member States are often not geared to the transnational structure of the companies taking the decisions, which may lead to unequal treatment of employees in different states.	The central management shall be responsible for creating the conditions and means (incl. financial) necessary for the setting up of a European Works Council or an information and consultation procedure	Size related exemption	Directive only applicable in the case of at least 1000 employees in the MS and at least 150 employees in each of at least two MS.
<b>Directive 2002/15/EC</b> of the European Parliament and of the Council of 11 March 2002 on the organisation of the working time of persons performing mobile road transport activities	Employment conditions	No regulation covering working time of drivers other than rest periods and driving times and no agreement has been reached on this between social partners	Employers shall be responsible for recording the working time of mobile workers. Employers shall upon request provide mobile workers with copies of the records of hours worked. Records shall be kept for at least two years after the end of the period covered.	Temporal Exemption	Not applicable for self employed drivers until 2009
<b>Council Directive 98/59/EC</b> of 20 July 1998 on the approximation of the laws of the Member States relating to collective redundancies	Employment conditions	Differences still remain between the provisions in force in the Member States concerning the practical arrangements and procedures for collective redundancies	Hold consultations with workers' representatives, provide written information on reasons, number, selection criteria etc.	Size related exemption	The procedure is only applicable if at least 10 dismissals are carried out in companies with 20-100 employees or 10% of employees in companies with 100-300 employees

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
		and the measures designed to alleviate the consequences of redundancy for workers, which can have a direct effect on the functioning of the internal market			
<b>Directive 2003/88/EC</b> of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time	Employment conditions	Improvement of workers' safety, hygiene and health at work should not be subordinated to purely economic considerations, workers need rest periods, long periods of nightwork is detrimental to workers health and can endanger safety at the workplace.	Take prevailing laws on working time into account. An employer who intends to organise work according to a certain pattern (should) take account of the general principle of adapting work to the worker, with a view, in particular, to alleviating monotonous work and work at a predetermined work-rate, and of safety and health requirements. An employer who regularly uses night workers (should) bring this information to the attention of the competent authorities if they so request. Employer should keep up-to-date records of all workers who work more than 48 hours over a seven-day period and place the records at the disposal of the competent authorities. the employer provides the competent authorities at their request with information on cases in which agreement has been given by workers to perform work exceeding 48 hours over a period of seven days.	Only a reference to SMEs	Directives adopted to improve working environment are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings.
<b>Directive 2002/14/EC</b> of the European Parliament and of the Council of 11 March 2002 establishing a general framework for informing and consulting employees in the European Community - Joint declaration of the European Parliament, the Council and the Commission on employee representation	Employment conditions	The existing legal frameworks at national and Community level intended to ensure that employees are involved in the affairs of the undertaking employing them and in decisions which affect them has not always prevented serious decisions affecting employees from being taken and made public without adequate information and consultations procedures	To carry out information and consultation with employees/employee representatives on the development of the company, development of employment within the company and major changes that might affect these.	Size related exemption	The purpose of this general framework is also to avoid any administrative, financial or legal constraints which would hinder the creation and development of small and medium-sized undertakings. To this end, the scope of this Directive should be restricted, according to the choice made by Member States, to undertakings with at least 50 employees or establishments employing at least 20 employees. Member States shall determine the method for calculating the thresholds of employees employed.
				Temporal Exemption	A Member State in which there is no system of information and consultation of employees, nor a system of employee representation at the workplace a may limit the application of the

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
		having been implemented beforehand; There is a need to strengthen dialogue and promote mutual trust within undertakings; Timely information and consultation is a prerequisite for the success of the restructuring and adaptation of undertakings to new conditions; The existing legal frameworks for employee information and consultation at Community and national level tend to adopt an excessively a posteriori approach to the process of change, neglect the economic aspects of decisions taken and do not contribute either to genuine anticipation of employment developments within the undertaking or to risk prevention.			national provisions implementing this Directive to undertakings employing at least 150 employees or establishments employing at least 100 employees until 23 March 2007 and during the following year undertakings employing at least 100 employees or establishments employing at least 50 employees.
<b>Council Directive 1999/70/EC</b> of 28 June 1999 concerning the framework agreement on fixed-term work concluded by ETUC, UNICE and CEEP	Employment conditions	ensure equal treatment of workers and to prevent abuse arising from the use of successive employment contracts or relationships	Employers shall inform fixed-term workers about vacancies; employers should facilitate access to appropriate training opportunities; firms should inform workers' representative bodies about fixed-term work in the undertaking	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints; several clauses of the agreement refer to national provisions allowing the needs of SMEs.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Council Directive 97/81/EC</b> of 15 December 1997 concerning the Framework Agreement on part-time work concluded by UNICE, CEEP and the ETUC - Annex : Framework agreement on part-time work	Employment conditions	enable more flexible working environment; eliminate discrimination against part-time workers; improve the quality of part-time work	Companies should 1) Enable the transfer for workers from full-time to part-time work (and vice versa) and facilitate access to part-time work at all levels of the firm 2) Provide information on the availability of internal part-time/full-time jobs and inform workers' representatives on part-time working	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints
<b>Council Directive 96/34/EC</b> of 3 June 1996 on the framework agreement on parental leave concluded by UNICE, CEEP and the ETUC	Employment conditions	facilitate the reconciliation of parental and professional responsibilities for working parents	Administrative costs to adjust to new rights/formalities); organisational issues when rights are exercised	Special treatment	Member States may authorize special arrangements to meet the operational and organizational requirements of small undertakings, allowing them to grant exemptions/reductions for parental leave for small businesses
<b>Council Directive 94/33/EC</b> of 22 June 1994 on the protection of young people at work	Employment conditions	adjust labour regulations applicable to young workers	employers have to protect the safety and health of young people; assess risks for young persons before commencing activity; inform of possible risks; involve the protective and preventive services in the health measures taken	Only a reference to SMEs	Directives shall avoid imposing administrative, financial and legal constraints
<b>Council Directive 2001/23/EC</b> of 12 March 2001 on the approximation of the laws of the Member States relating to the safeguarding of employees' rights in the event of transfers of undertakings, businesses or parts of undertakings or businesses	Employment conditions	Differences still remain in the Member States as regards the extent of the protection of employees in the event of a change of employer, and these differences should be reduced.	The transferor and transferee shall be required to inform in good time the representatives of their respective employees affected by the transfer about the circumstances and effects of the transfer on employment contracts and conditions. They shall consult the representatives of employees on measures envisaged with a view to reaching an agreement.	Size related exemption	Member States may limit the obligations to undertakings or businesses which, in terms of the number of employees, meet the conditions for the election or nomination of a collegiate body representing the employees.
<b>Council Directive 90/496/EEC</b> of 24 September 1990 on nutrition labelling for foodstuffs	Consumer protection	Nutrition labelling formats and contents differed across MSs, hampering the transparency of such labelling towards European consumers.	Prescribing harmonised format and content for nutrition labelling. Labelling is optional, however, unless a nutritional claim appears e.g. in advertising.	Special treatment	The Directive encourages interested parties, especially small and medium-sized undertakings, to provide nutrition labelling for as many products as possible.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Directive 98/6/EC</b> of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers	Consumer protection	The indication of unit price is necessary for consumers to easily compare products.	The obligation to indicate (including advertisements) selling price and the unit price for all products.	Temporal Exemption	Member States should be allowed to refrain from applying the obligation for certain small retail businesses to indicate the unit price during an appropriate transitional period, as this may entail an excessive burden under certain circumstances (because of the number of products on sale, the sales area, the nature of the place of sale, specific conditions of sale where the product is not directly accessible for the consumer or certain forms of business, such as certain types of itinerant trade), though the length of time was not set.
<b>Commission Regulation (EC) No 1981/2006</b> of 22 December 2006 on detailed rules for the implementation of Article 32 of <b>Regulation (EC) No 1829/2003</b> of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms	Consumer and health protection	The necessity to set out the contributions that CRL may ask from applicants, and the modalities of establishing national reference laboratories.	For each application, a flat-rate contribution of EUR 30 000 shall be paid by the applicant to the CRL. An additional contribution of EUR 60 000 shall be paid for a full validation procedure of a method of detection and identification for a single GMO event. Additional contribution may be requested if the costs significantly exceed this.	Special treatment	Where the applicant is a SME the financial contributions are reduced by 50 %.
<b>Regulation (EC) No 852/2004</b> of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs	Consumer and health protection	Need to devise a coherent legislative framework to ensure food safety on the single market.	Hygiene requirements (based on the HACCP principles) for food business operators to be ensured in all stages of production, processing and distribution of food under their control (compliance with microbiological criteria for foodstuffs; procedures necessary to meet targets set to achieve the objectives of the Regulation; compliance with temperature control requirements for foodstuffs; maintenance of the cold chain; sampling and analysis).	Size related exemption	small producers supplying direct to consumers are exempt from the Regulation (instead national legislation applies). The requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.

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Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
<b>Regulation (EC) No 853/2004</b> of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin	Consumer and health protection	Need to devise a coherent legislative framework to ensure food safety on the single market.	Establishments handling products of animal origin must be approved by the competent authority in their Member State. Products of animal origin must be given a health mark or an identification mark. Information obligations to ensure that slaughterhouse operators receive food chain information on all animals except wild game.	Size related exemption	small producers supplying direct to consumers are exempt from the Regulation (instead national legislation applies), provided Regulation 852/2004 is adhered to
<b>Commission Regulation (EC) No 2023/2006</b> of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food	Consumer and health protection	variations in approaches within Member States	Companies active in manufacture, processing and distribution of materials and articles intended to come into contact with foodstuff shall establish, implement and ensure adherence to an effective and documented quality assurance system. They shall establish and maintain an effective quality control system, and appropriate documentation in paper or electronic format. Printed surfaces shall not come into direct contact with food.	Only a reference to SMEs	The legislation specifies that rules on GMP should be applied proportionately to avoid undue burdens for small businesses.
<b>Commission Regulation (EC) No 282/2008</b> of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006	Consumer and health protection	Plastic packaging waste may contain residues from previous use, contaminants from misuse and contaminants from non-authorised substances.	Recycled material may only come from authorised recycling process. The authorisation holder shall comply with the conditions or restrictions attached to the authorisation. The authorised recycling process shall be managed by an appropriate quality assurance system.	Only a reference to SMEs	Audits should be made in the most cost effective manner possible to keep to a minimum the administrative and economic burden to competent authorities and small and medium enterprises.
<b>Council Directive 86/635/EEC</b> of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions	Company law	variations in systems of reporting of annual accounts	Prescriptions on the annual accounts (layout, terminology, etc.)	Only a reference to SMEs	No SME clause. But recital mentions that, in the light of experience, if relief for SMEs were to prove necessary it would be possible to provide for it in subsequent coordination.
<b>Directive 2000/35/EC</b> of the European Parliament and of the Council of 29 June 2000 on combating late payment in commercial transactions	Company law	Late payments constitute a major obstacle to the free movement of goods and services in the single market and could substantially distort competition. The resulting	The Directive does not contain obligations for creditors that are SMEs	Special treatment	Where contractual conditions regarding late payments are found to be grossly unfair, SMEs or bodies representing SMEs may take legal action to remove these conditions.

Legislation title	Policy area	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Type of SME provision	Description of provision
		administrative and financial burdens impede cross-border trade. Small and medium-sized enterprises (SMEs) and the craft sector are most vulnerable here.			
<b>Directive 2003/6/EC</b> of the European Parliament and of the Council of 28 January 2003 on insider dealing and market manipulation (market abuse) (amended by Directive 2008/26/EC)	Company law	The legal framework for protecting market integrity is incomplete. At European level, there are no common provisions against market manipulation. At Member State level, the rules vary greatly and legal requirements differ according to jurisdiction. These differences may distort competition in financial markets.	Member States shall ensure that issuers of financial instruments inform the public as soon as possible of inside information which directly concerns the said issuers. Member States shall ensure that issuers, for an appropriate period, post on their Internet sites all inside information that they are required to disclose publicly. Member States shall require that issuers, or persons acting on their behalf or for their account, draw up a list of those persons working for them, under a contract of employment or otherwise, who have access to inside information. Issuers and persons acting on their behalf or for their account shall regularly update this list and transmit it to the competent authority whenever the latter requests it. Member States shall ensure that market operators adopt structural provisions aimed at preventing and detecting market manipulation practices. Etc.	Only a reference to SMEs	In exercising its implementing powers in accordance with the Directive, the Commission should respect the balance of costs and benefits to market participants on a long-term basis (including small and medium-sized businesses and small investors).
<b>Council Regulation (EC) No 2157/2001</b> of 8 October 2001 on the Statute for a European company (SE)	Company law	The legal framework within which business must be carried on in the Community is still based largely on national laws which forms a considerable obstacle to the creation of groups of companies from different Member States.	Minimum capital requirement. Detailed provisions for the creation of SEs, e.g: management or administrative organ shall draw up a transfer proposal if registered office of an SE is transferred to another Member State, management draw up draft terms of merger if SE is created that way, comply with law applicable to public limited-liability companies in the Member State in which the SE establishes its registered office etc	Only a reference to SMEs	To ensure that companies that form an SE are of reasonable size a minimum amount of capital should be set so that they have sufficient assets without making it difficult for small and medium-sized undertakings to form SEs.

## ANNEX 2: RESULTS OF REVIEW OF 5 EU PROGRAMMES

**Table A2.1: Background information**

Programme	Period	Related legislation	Budget	Sector
MEDIA	2007-2013	Decision No 1718/2006/EC of the European Parliament and of the Council of 15 November 2006 concerning the implementation of a programme of support for the European audiovisual sector (MEDIA 2007)	755 M€	Culture and Media
FP7	2007-2013	Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)	Co-operation (circa €32.3 billion), "Ideas" (circa €7.5 billion), "People" (circa €4.7 billion) and "Capacities" (circa €4.3 billion).	R&D, ICT
ESF	2007-2013	Regulation (EC) No 1081/2006 of the European Parliament and of the Council of 5 July 2006 on the European Social Fund and repealing Regulation (EC) No 1784/1999; COUNCIL REGULATION (EC) No 1083/2006 of 11 July 2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund and repealing Regulation (EC) No 1260/1999	EUR 16 Bn	Employment
ECO Innovation (part of CIP-EIP)	2007-2013	Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013)	440 M€ (1/5 of the 2.2 bn € EIP budget)	Enterprise and industry, environment
Leonardo da Vinci (part of LLLP)	2007-2013	Decision No 1720/2006/EC of the European Parliament and of the Council of 15 November 2006 establishing an action programme in the field of lifelong learning	Min 1.7 bn € (25% of total programme budget)	Education

**Table A2.2: Review results**

Programme	Objectives of the programme	Actions	Requirements to obtain funds	Is there particular focus on SMEs?	Type of SME measure	Description	Rationale for the SME consideration
MEDIA	To strive for a stronger European audiovisual sector, to increase the circulation of European audiovisual works inside and outside the European Union and to strengthen the competitiveness of the European audiovisual sector by facilitating access to financing and promoting use of digital technologies	Finances: training of professionals; development of production projects and companies; distribution of cinematographic works and audiovisual programmes; promotion of cinematographic works and audiovisual programmes (including the support for film festivals) and pilot projects for new technologies	Varies depending on action. The actions targeting SMEs (development, distribution) have requirements such as: having relevant experience, adequate financial and technical capacities, be registered as a company for a certain amount of time and owning rights to material. In some cases company consortia are required.	Yes, the legislation text mentions that particularly SMEs should be supported, especially with funds for development and distribution.	None	Not applicable	The European audiovisual sector is characterized by a large number of SMEs and very small enterprises with chronic undercapitalisation. Increased transparency and dissemination of information concerning the European audiovisual market can make operators in the sector, and especially SMEs, more competitive.

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Programme	Objectives of the programme	Actions	Requirements to obtain funds	Is there particular focus on SMEs?	Type of SME measure	Description	Rationale for the SME consideration
FP7	To fund European research, respond to Europe's employment needs and competitiveness through the sub-programmes "Co-operation", "Ideas", "People" and "Capacities".	The sub-programmes fund research within the following areas: Cooperation (health, food/agriculture/biotech, ICT, nanosciences, energy, environment, transport, socio-economic sciences, space, and security). Ideas: supporting "investigator-driven" research carried out across all fields by individual, national or transnational teams in competition at the European level. People: training and career development of researchers. Capacities: research infrastructures, regional research driven clusters; the development of a full research potential in the Community's convergence and outermost regions; research for the benefit of SMEs, science in Society, support to coherent development of policies and international cooperation.	At least three independent legal entities in three different Member States or associated countries. Additional requirements laid down in specific programmes and work programmes. Submission of periodic progress reports and proof of existing co-financing. Application form in two parts with detailed information on project, company, cooperation partners etc.	Yes, SME consideration throughout the programme in the shape of "what is the SME benefit of the respective action". Particular focus within "capacities" programme that contains funding of research for the benefit of SMEs and cooperation programme, where SME participation in research actions will be encouraged. Consultation with "sounding board" of smaller actors during the preparation of FP7.	SME participation targets/monitoring	Monitoring of SME participation in programme. Aim of at least 15% of funding under Cooperation to go to SMEs.	Increase SME participation in research activities. Need for a strengthened and simplified approach to research funding, which is particularly important for SMEs.
					Preferential treatment	Higher funding rates for SMEs (max 75% instead of 50% of eligible costs), a wider choice of funding schemes	

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Programme	Objectives of the programme	Actions	Requirements to obtain funds	Is there particular focus on SMEs?	Type of SME measure	Description	Rationale for the SME consideration
					Simplified obligation	Cover the entire funding cycle, including the various elements of funding schemes, administrative and financial rules, procedures, readability and user-friendliness of documents etc.	
					Tailor made information, coaching, training	61 NCPs specifically for SMEs, SME Techweb –a site for information for SMEs in FP7	
ESF	To reduce differences in prosperity and living standards across EU Member States by promoting economic and social cohesion and improving employment and job opportunities	Adapting workers and enterprises: lifelong learning schemes, designing and spreading innovative working organisations; access to employment for job seekers, the unemployed, women and migrants; social integration of disadvantaged people and combating discrimination in the job market; strengthening human capital by reforming education systems and setting up a network of teaching establishments	ESF funding is available through operational programmes in the Member States, therefore application requirements vary	Yes – regulation recognises the particular role of SMEs in creating new jobs and job places. The new ESF interventions will focus on giving direct assistance to companies and especially SMEs	None on EU level, possibly in specific Member States.	Not applicable	SMEs have specific need to anticipate and adapt to economic changes

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Programme	Objectives of the programme	Actions	Requirements to obtain funds	Is there particular focus on SMEs?	Type of SME measure	Description	Rationale for the SME consideration
ECO-Innovation (part of CIP-EIP)	Supporting the first application and further market uptake of eco-innovative products and services in Europe, helping to overcome barriers that hamper their commercial success.	Supports eco-innovative projects, particularly in the fields of: materials recycling, food and drink, building and construction and greening business/smart purchasing	Legal person based in EU/EEA/partner countries. Application form with detailed information on the technology/solution, budget and participants. Legal documents, financial statements and declaration of honour to be attached.	Yes, priority will be given to SMEs, though call is open for all legal persons.	Preferential treatment	Priority will be given to SMEs when awarding grants	None explicit but likely to do with the general focus on SMEs within the EIP.
Leonardo da Vinci (part of LLLP)	Address the teaching and learning needs of all those in vocational education and training, as well as the institutions and organisations providing or facilitating such education and training	Transnational mobility (placements in enterprises or in training institutions), European projects focusing on the development or the transfer of innovation and networks	Proof of sufficient financial capacity (annual accounts or external audit report depending on size of grant). For multilateral projects: a detailed estimated budget. Paper application. Partner or consortia in several MS. Additional requirements vary between actions.	Yes, legislation text recognizes the importance of improving the attractiveness of Community action for SMEs	None	Not applicable	SMEs play an important role in the European economy, but participation by SMEs in the Leonardo da Vinci programme has been limited.

## ANNEX 3: RESULTS OF REVIEW OF 48 PIECES OF EU LEGISLATION WITHOUT SME MEASURES

Legislation title	Policy area	Aim of legislation	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Relevant for significant number of SMEs (low, medium, high)	Scale of burden imposed (low, medium, high)
<b>Council Directive 2008/8/EC</b> of 12 February 2008 amending Directive 2006/112/EC as regards the place of supply of services	Taxation	Introduce place of VAT taxation for supply of services in the place where recipient is established	correct taxation systems based on the destination principle for the supply of services	companies have to fill in VAT return statement stating the taxable and the non-taxable legal persons to whom the service was supplied, the amount traded; taxable persons not established within the Community have to keep records of VAT for 10 years after the transaction was made	high	medium
<b>Council Directive 2005/19/EC</b> of 17 February 2005 amending Directive 90/434/EEC on the common system of taxation applicable to mergers, divisions, transfers of assets and exchanges of shares concerning companies of different Member States	Taxation	to improve and extend tax deferral system for cross-border mergers, divisions of firms, transfers of assets and exchanges of shares; further improve rules governing the internal market	add other companies not included in Directive 90/434/EEC (co-operatives, mutual firms, etc); cover "partial division"/"split-off" operations	not relevant	low	low
<b>Council Directive 2004/106/EC</b> of 16 November 2004 amending Directives 77/799/EEC concerning mutual assistance by the competent authorities of the Member States in the field of direct taxation, certain excise duties and taxation of insurance premiums and 92/12/EEC on the general arrangements for products subject to excise duty and on the holding, movement	Taxation	enhance administrative cooperation between Community tax authorities	slack cooperation between Community tax authorities	not relevant	low	low

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Legislation title	Policy area	Aim of legislation	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Relevant for significant number of SMEs (low, medium, high)	Scale of burden imposed (low, medium, high)
and monitoring of such products						
<b>Council Directive 2003/123/EC</b> of 22 December 2003 amending Directive 90/435/EEC on the common system of taxation applicable in the case of parent companies and subsidiaries of different Member States	Taxation	improve the operation of the Parent-Subsidiary Directive 90/435/EEC; further improve the rules governing the internal market	broaden the list of firms covered by the amended directive; relax the conditions for exempting dividends from withholding tax (reduction of the participation threshold); eliminating double taxation for subsidiaries of subsidiary companies	not relevant	low	low
<b>Council Directive 2003/49/EC</b> of 3 June 2003 on a common system of taxation applicable to interest and royalty payments made between associated companies of different Member States	Taxation	to abolish withholding taxes on royalty payments and interest payments arising in a Member State	eliminate withholding tax obstacles in the area of cross-border interest and royalty payments within a group of companies	not relevant	low	low
<b>Council Directive 2003/48/EC</b> of 3 June 2003 on taxation of savings income in the form of interest payments	Taxation	ensure effective taxation of interest income from cross-border investment of savings that is paid to individuals within the EU	reduce distortions in the capital movements between Member States; improve governing rules of the internal market	paying agents have to report the identity of the beneficiary, the interest payment within a certain time frame	low	low
<b>Regulation (EC) No 1552/2005</b> of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises	Statistics	The creation of common statistical standards that permit the production of harmonised data on vocational training in enterprises	There are no comparable statistics on vocational training, which is a key component for developing and monitoring of lifelong learning strategies.	Respond to a survey on vocational training every 5 years	high	low

Legislation title	Policy area	Aim of legislation	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Relevant for significant number of SMEs (low, medium, high)	Scale of burden imposed (low, medium, high)
<b>Directive 2004/37/EC</b> of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of <b>Council Directive 89/391/EEC</b> )	Occupational health and safety	sets out the exposure limit values as well as preventive measures for protecting workers who have been exposed to carcinogens and mutagens	reduce risks associated with mutagens and carcinogens	companies shall reduce and replace the use of a carcinogen or mutagen whenever possible; ensure the prevention and reduction of exposure; provide information for the competent authority; ensure protective measures in case of unforeseeable exposure & foreseeable exposure; must control access to risk areas; ensure hygiene and personal protection measures; Informing, training and consulting workers; ensure health monitoring; Record-keeping for at least 40 years after the end of exposure;	low	high
<b>Directive 2003/105/EC</b> of the European Parliament and of the Council of 16 December 2003 amending <b>Council Directive 96/82/EC</b> on the control of major-accident hazards involving dangerous substances	Occupational health and safety	prevention of major accidents which involve dangerous substances	to cover risks arising from storage and processing activities in mining, from pyrotechnic and explosive substances and from the storage of ammonium nitrate and ammonium nitrate based fertilizers	companies shall report to the competent authorities the substances used for inventory purposes; emergency and prevention measures in case of accident;	low	high
<b>Directive 2000/54/EC</b> of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of <b>Directive 89/391/EEC</b> )	Occupational health and safety	establish minimum standards to guarantee a better standard of safety and health for workers exposed to biological agents at work	reduce exposure to biological agents at work	companies must replace and reduce exposure to agents whenever possible; information for the competent authority on activity involving risks; information for competent authority if accidents; ensure hygiene and individual protection; information and training of workers; list of workers exposed to group 3 and/or 4 agents to be kept for a minimum number of years; health surveillance	medium	high

Legislation title	Policy area	Aim of legislation	The problem that the legislation was designed to address	Nature of obligation imposed on companies	Relevant for significant number of SMEs (low, medium, high)	Scale of burden imposed (low, medium, high)
<b>Regulation (EC) No 561/2006</b> of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending <b>Council Regulations (EEC) No 3821/85</b> and <b>(EC) No 2135/98</b> and repealing <b>Council Regulation (EEC) No 3820/85</b>	Occupational health and safety	rules on driving times, breaks and rest periods for drivers engaged in the carriage of goods and passengers by road	to avoid distortion of competition, improve road safety and driver working conditions within the Community	employers should ensure employees respect the minimum standards for driving and rest periods	medium	medium
<b>Council Directive 92/75/EEC</b> of 22 September 1992 on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances	Internal market	To create a Community wide system of energy labelling of household appliances in order to remove a barrier to trade; also to promote the use of more energy efficient appliances	Lack of a Community-wide system for energy labelling of household appliances, and instead a number of different systems in operation, creating barriers to trade.	Labelling and an accompanying product fiche providing technical proof of the labelling information, to be including in the product brochure	medium	low
<b>Directive 2007/47/EC</b> of the European Parliament and of the Council of 5 September 2007 amending <b>Council Directive 90/385/EEC</b> on the approximation of the laws of the Member States relating to active implantable medical devices, <b>Council Directive 93/42/EEC</b> concerning medical devices and <b>Directive 98/8/EC</b> concerning the placing of biocidal products on the market	Internal market	to develop a single market in medical equipment and to ensure a high level of health protection	lack of a community-wide system for testing and authorising medical equipment, creating a barrier to trade	All medical products must bear a CE marking, and Member States are not allowed to prevent products with a CE marking to be placed on the market. To get a CE marking, firms must have a conformity assessment for each product completed by a Notified Body. The conformity assessment includes consideration of materials used, the compatibility of materials with biological tissue. This includes submission of clinical data	low	high
<b>Directive 2006/42/EC</b> of the European Parliament and of the Council of 17 May 2006 on machinery, and	Internal market	To develop a single market in machinery, and to ensure the safety of consumers and	lack of a community-wide system for testing and authorising machinery, creating a barrier to trade.	Manufacturers must undertake a risk assessment of their product to determine the H&S requirements, and design in mitigation measures to protect users/ consumers. A file on	medium	medium

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amending Directive 95/16/EC		employees	By implication variable standards in H&S testing of machinery	the product must then be submitted to a NB for a conformity assessment, after which the product can use a CE marking.		
<b>Directive 2004/28/EC</b> of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products	Internal market	to develop a single market in veterinary medicinal products, and to ensure a high standard of animal health protection	a lack of mutual recognition of authorisations of veterinary medicinal products between Member States	All veterinary medicinal products must be authorised by either a CA within a Member State or the EMA. Authorisation required submission of a range of information including composition, manufacturing method, safe usage etc. Clinical trial data is required, unless it can be demonstrated that ingredients or products have been in use for a long period	low	high
<b>Directive 2004/27/EC</b> of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use	Internal market	to develop a single market in medicinal products, and to ensure a high standard of health protection	a lack of mutual recognition of authorisations of medicinal products between Member States, differences in labelling and packaging requirements	All medicinal products must be authorised in order to be placed on the market. In order to obtain authorisation, businesses must submit a request to their CA, or the EMA. Requests must include a large amount of supporting information covering composition, manufacturing method, safe usage etc. Generally data on clinical trials is required, unless the product or its active ingredients have been in use in the EU for a number of years (i.e. has a proven safety, efficacy etc). MS may request samples for their own testing purposes. There are allowances for homeopathic medicines. The Directive also sets out labelling and packaging requirements	low	high
<b>Directive 2004/24/EC</b> of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use	Internal market	to develop a single market in medicinal products, in this case herbal medicines, and to ensure a high standard of health protection	a lack of mutual recognition of authorisations of herbal medicines between Member States acting as a barrier to trade	If herbal medicinal products are able to satisfy the requirements of Directive 2001/83/EC then this Directive does not apply. However where they are not then there is still a requirement for authorisation, but requirements are reduced. Products do not have to provide evidence of clinical trials provided it can be demonstrated that they have been in use for at least 15 years (traditional usage).	low	medium

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<b>Directive 2002/92/EC</b> of the European Parliament and of the Council of 9 December 2002 on insurance mediation	Internal market	to develop a SM in insurance mediation, and to protect consumers	Differences in national legal systems made it hard for insurance intermediaries (banks, brokers, motor car dealers) to provide services outside of their country of origin	all intermediaries are required to register with the CA in their Member State. Registration is dependent upon meeting certain criteria covering professionalism, repute, degree of professional indemnity insurance, and possessing sufficient financial capability. membership of the register is subject to regular review. Intermediaries are also required to provide customers with information	high	high
<b>Directive 96/74/EC</b> of the European Parliament and of the Council of 16 December 1996 on textile names	Internal market	to develop the SM in textiles	a lack of a harmonised system for labelling textiles	the Directive sets out the names that can be used and the technical specifications that enable the use of these names	medium	low
<b>Directive 94/11/EC</b> of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer	Internal market	to develop a single market in footwear products	Different labelling systems in Member States created a barrier to trade; lack of clarity in labelling needed in order to protect consumer interests	sets out labelling requirements on footwear regarding information about the material used. No other requirements	medium	low
<b>Regulation (EC) No 1013/2006</b> of the European Parliament and of the Council of 14 June 2006 on shipments of waste	Environmental protection	control of shipments of waste in a way which takes account of the need to preserve, protect and improve the quality of the environment and human health	lack of more uniform application of the Regulation throughout the Community risking human, animal and environmental health.	Notification, reporting and contracts	medium	medium

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<b>Regulation (EC) No 166/2006</b> of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending <b>Council Directives 91/689/EEC and 96/61/EC</b>	Environmental protection	To approximate the laws of the Member States on the controlled management of hazardous waste	Mixing of different categories of hazardous waste or mixing hazardous waste with non-hazardous waste. Lack of conditions for different forms of waste recovery	Registration, reporting,	medium	high
<b>Directive 2006/118/EC</b> of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration	Environmental protection	Protection of groundwater against pollution and deterioration to protect the environment as a whole, and human health in particular.	Lack of quality standards Increasing trend of water pollution due to human activity	identify risks and undertake measures. check ground water permit	low	medium
<b>Directive 2006/11/EC</b> of the European Parliament and of the Council of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community	Environmental protection	Protection aquatic environment from pollution, particularly that caused by certain persistent, toxic and bioaccumulable substances.	Lack of coordination of several conventions designed to protect international watercourses and the marine environment from pollution.	Authorisation application	low	medium
<b>Directive 2003/108/EC</b> of the European Parliament and of the Council of 8 December 2003 amending <b>Directive 2002/96/EC</b> on waste electrical and electronic equipment (WEEE)	Environmental protection	To reduce the economic risk for producers who have the financial responsibility for the collection, treatment, re-use, recovery and recycling of WEEE	Article 9 of Directive 2002/96/EC, found that the take-back obligation for WEEE put on the market in the past creates a retroactive liability for which no provision was made and which is likely to expose certain producers to serious economic risks.	information and reporting to MS. Communication to consumers	high	high

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<b>Directive 2000/14/EC</b> of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors	Environmental protection	To promote the smooth functioning of the internal market and to improve the health and well-being of the population by reducing the noise emitted by equipment used outdoors.	Noise, as one of main local environmental problems in Europe. Lack of informed choice on equipment	certification, declaration of conformity,	medium	low
<b>Council Directive 1999/31/EC</b> of 26 April 1999 on the landfill of waste	Environmental protection	to prevent or reduce the adverse effects of the landfill of waste on the environment, in particular on surface water, groundwater, soil, air and human health	Lack of appropriate measures to avoid dumping, abandonment and uncontrolled disposal of waste disparities between technical standards. High quantity and hazardous nature of waste going to landfill	Licensing, reporting and meeting minimum standards	high	high
<b>Council Directive 91/689/EEC</b> of 12 December 1991 on hazardous waste	Environmental protection	harmonize laws of MS regarding the controlled management of hazardous waste and supplements Directive 2006/12/EC		properly packaged and label waste products, do not mix different forms of waste	medium	high
<b>Directive 2001/81/EC</b> of the European Parliament and of the Council of 23 October 2001 on national emission ceilings for certain atmospheric pollutants	Environmental protection	Member States must draw up programmes for the progressive reduction of their annual national emissions of acid depositions and ground level ozone	acidification, eutrophication and tropospheric ozone formation caused by the emission of pollutants - sulphur dioxide (SO <sub>2</sub> ), nitrogen oxide (NO <sub>x</sub> ), volatile organic compounds (VOC) and ammonia (NH <sub>3</sub> )	primarily aimed at level of Member States	low	low

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<b>Council Directive 1999/30/EC</b> of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air	Environmental protection	ensure that concentrations of sulphur dioxide, nitrogen dioxide, PM10, lead and other pollutants in ambient air do not exceed the limit values	variations in national standards regarding levels of sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air	primarily aimed at level of Member States	low	low
<b>Directive 2002/95/EC</b> of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	Environmental protection	need to encourage the design and production of electrical and electronic equipment which take into account and facilitate dismantling and recovery, in particular the reuse and recycling of waste electrical and electronic equipment	variations in approaches towards the use of hazardous substances in electrical equipment	Producers must not use hazardous substances, make provision for the collection of waste that is not from private households, and finance the collection, treatment, recovery and environmentally sound disposal of waste electrical and electronic equipment	medium	high
<b>Council Directive 75/439/EEC</b> of 16 June 1975 on the disposal of waste oils	Environmental protection	create harmonized legislation to create provisions relating to the disposal of waste oils with the essential objectives of the protection of the environment against the harmful effects caused by the discharge, deposit or treatment of these oils;	disparity between the provisions on the disposal of waste oils already applicable or in preparation in the various Member States may create unequal conditions of competition and thus directly affect the functioning of the common market	any undertaking which disposes of waste oils must obtain a permit	low	medium
<b>Council Directive 91/271/EEC</b> of 21 May 1991 concerning urban wastewater treatment	Environmental protection	to prevent the environment from being adversely affected by the disposal of insufficiently-treated urban waste water, there is a general need for secondary treatment of urban waste water	variations in national standards regarding urban wastewater	Treatment of wastewater to minimum standards.	low	high

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<b>Directive 2006/12/EC replacing Council Directive 75/442/EEC</b> of 15 July 1975 on waste	Environmental protection	prohibit the abandonment, dumping or uncontrolled disposal of waste, and must promote waste prevention, recycling and processing for re-use	need to reduce the environmental damage from the disposal of waste and to encourage the use of recovered materials	waste must be handled by a private or public waste collector or a disposal undertaking,	high	high
<b>Directive 2004/35/CE</b> of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage	Environmental protection	establish a framework of environmental liability based on the 'polluter-pays' principle, to prevent and remedy environmental damage	Failure to remediate existing sites in the Community, could result in increased site contamination and greater loss of biodiversity in the future, posing significant health risks.	Operators carrying out "hazardous" activities will be held strictly liable (i.e. no need to show fault or negligence) for preventing or restoring any damage caused by those activities to land, water and protected habitats and species.  In addition, operators carrying out other, less harmful, activities will be held liable when damage to protected habitats and species has been caused by their fault or negligence.	medium	high
<b>Council Directive 91/533/EEC</b> of 14 October 1991 on an employer's obligation to inform employees of the conditions applicable to the contract or employment relationship	Employment conditions	set up the minimum information employers shall provide employees within the framework of a contract or employment relationship	to protect employees against possible infringements of their rights	companies shall adapt their HR procedures for employment contracts; communicate with employees within a determined timeframe	high	high
<b>Directive 2002/73/EC</b> of the European Parliament and of the Council of 23 September 2002 amending Council Directive 76/207/EEC on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training and promotion, and working conditions (Text with EEA relevance)	Employment conditions	To ensure equal treatment for men and women in respect of access to employment, vocational training and career advancement, and working conditions	to define sexual harassment	employers should promote equal treatment; employers should provide workers and their representatives with appropriate information on equal treatment (e.g. Statistics)	high	high

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<b>Directive 95/46/EC</b> of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data	Consumer and health protection	set up a regulatory framework to protect the rights and freedoms of persons with respect to the processing of personal data; member states may determine more precisely the conditions under which the processing of personal data is lawful;	avoid the abusive use of personal data	companies must process in a fairly and lawfully way; they have to collect it for specified, explicit and legitimate purposes; companies have ensure the confidentiality and security of processing; prior to processing data, companies must notify the national supervisory authority	high	high
<b>Regulation (EC) No 1924/2006</b> of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods	Consumer and health protection	improve the protection of consumers' health and rights	prohibit misleading and false advertising which may adversely affect the health of consumers	companies must submit an application to the Member State to obtain for an authorisation for a new claim or amend the existing list; companies must ensure that claims have scientific substantiation;	medium	high
<b>Regulation (EC) No 1830/2003</b> of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC	Consumer and health protection	inform consumers through compulsory labelling; create a "safety net" based on the traceability of products	harmonise disparate legislation on the labelling of GMOs and traceability measures	companies have to report specific information in writing when transmitting the product to the operator (indication that the products consist of or contain GMOs, unique alphanumeric identifiers assigned to the GMOs contained in the products); companies need to ensure adequate labelling containing mandatory indications	low	medium
<b>Regulation (EC) No 258/97</b> of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients	Consumer and health protection	ensure a high level of food safety for new foodstuffs	prevent novel foods and ingredients from being a danger for consumers' health	companies shall submit a detailed request (specific details, summary of the dossier) to the Member State and the Commission; must submit the product to an initial assessment; must adopt correct labelling;	medium	medium

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<b>Directive 2000/13/EC</b> of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs	Consumer and health protection	ensure a high protection of consumers through adequate labelling, presentation and advertising of foodstuffs	inadequate labelling, presentation and advertising of pre-packaged foodstuffs may mislead consumers or give them abusive indications	companies have to provide specific labelling (labelling must include the name under which the product is sold, the list of ingredients, the quantity of ingredients or categories of ingredients expressed as a percentage, further requirements for perishable foodstuffs); companies have to follow the same protocol when presenting and advertising foodstuffs	medium	medium
<b>Directive 2003/89/EC</b> of the European Parliament and of the Council of 10 November 2003 amending <b>Directive 2000/13/EC</b> as regards indication of the ingredients present in foodstuffs	Consumer and health protection	to provide consumers, especially those suffering from food allergies or intolerances, with fuller information on the composition of products through more exhaustive labelling.	avoid the exposure of certain consumers prone to food allergy to risks in case of incomplete labelling in foodstuffs	companies have to provide adequate labelling for listed allergens	medium	low
<b>Council Directive 85/577/EEC</b> of 20 December 1985 to protect the consumer in respect of contracts negotiated away from business premises	Consumer and health protection	To protect consumers against dishonest business practices in connection with contracts negotiated away from business premises	prevent abuse of consumer in some particular types of commercial contracts	companies have to inform consumers in writing about their right to cancel the contract	high	medium
<b>European Parliament and Council Directive 94/35/EC</b> of 30 June 1994 on sweeteners for use in foodstuffs	Consumer and health protection	provide a list of authorised sweeteners for foodstuffs and their conditions of use	protect consumer's health; prevent consumers from being exposed to dangerous artificial sweeteners	compliance costs: companies have to provide specific indications for sales description and labelling	low	low
<b>European Parliament and Council Directive No 95/2/EC</b> of 20 February 1995 on food additives other than colours and sweeteners	Consumer and health protection	provide a list of authorised additives for foodstuffs and their conditions of use	complete existing legislation for additives other than colours, sweeteners and flour treatment agents; prevent the abusive use of substances in foodstuffs, which may pose a risk for consumers' health	companies have to use only authorised substances; compliance costs (especially information related costs) as companies need to be familiar with the list	low	low

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<b>Council Directive 89/108/EEC</b> of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption	Consumer and health protection	set up rules for the quick-freezing, packaging, labelling and inspection of quick-frozen foodstuffs	protect consumers' health; extend existing legislative rules to all quick-frozen foodstuffs	companies must ensure that products are carried out promptly; companies must ensure appropriate technical equipment and raw materials; companies cannot employ other substances than air, nitrogen or carbon dioxide meeting specific purity criteria for cryogenic media; companies need to comply with required temperature during transport and local distribution; companies must provide adequate packaging and labelling	medium	high
<b>Directive 2005/60/EC</b> of the European Parliament and of the Council of 26 October 2005 on the prevention of the use of the financial system for the purpose of money laundering and terrorist financing (Text with EEA relevance)	Company law	to prevent the use of the financial system for the purposes of money laundering or terrorist financing	variations in national rules regarding identifying money laundering	The Directive covers all businesses trading in goods over €15,000 per transaction (cash payment only), plus all credit and financial institutions and individuals (auditors etc). For all transactions, companies must verify the identity of their customer (customer due diligence); report suspicions of money laundering or terrorist financing to the public authorities; set up preventive systems within their organisations; keep these documents in their records for at least 5 years after the transaction; risk assessment and internal training and control	high	high

## ANNEX 4: CONSULTEES AND DOCUMENTARY EVIDENCE

### **Consultees**

The Directorates-General were consulted during the study:

- § DG Employment;
- § DG Environment;
- § DG Information Society and Media;
- § DG Transport and Energy;
- § DG Agriculture.

The following SME representative bodies were consulted during the study:

- § Business Europe;
- § UEAPME;
- § Eurochambres;
- § European Small Business Alliance.

Individuals from the following organisations attended the expert workshop meeting held on 29 May 2008:

- § Bundesministerium für Wirtschaft and Arbeit, Abteilung I/7 (Austria);
- § Administrative Simplification Agency (Belgium);
- § Bulgarian Small and Medium Enterprises Promotion Agency (Bulgaria);
- § Division for Better Business Regulation, Danish Commerce and Companies Agency (Denmark);
- § Direction du Commerce, de l'Artisanat, des Services et des Professions libérales (France);
- § IWP Institut für Wirtschafts- und Politikforschung (Germany);
- § Ministry of Development, General Secretariat of Industry (Greece);
- § Ministry of Economy and Transport (Hungary);
- § P&D Consulting (Italy);
- § Business Environment Improvement Division, Investment and Development Agency of Latvia (Latvia);
- § Development Policy Division, Ministry of Economy the Republic of Lithuania (Lithuania);
- § Ministère des Classes Moyennes, du Tourisme et du Logement (Luxembourg) ;
- § Ministry of Finance, Economy and Investment (Malta);
- § Ministry of Trade and Industry, Department of Regulatory Affairs and Shipping (Norway);

- § Department of Economic Regulations, Polish Ministry of Economy (Poland);
- § Chamber of Craft and Small Business of Slovenia (Slovenia);
- § Slovak Chamber of Commerce and Industry (Slovakia);
- § Ministry of Enterprise, Energy and Communication (Sweden);
- § Enterprise Directorate, Enterprise and Environment Outreach Team, Department for Business, Enterprise & Regulatory Reform (UK).

***Documentary evidence reviewed during the study:***

Eurostat (2008) Enterprises by size class: overview of SMEs in the EU;

COM(2005) 551 Implementing The Community Lisbon Programme : Modern SME Policy For Growth And Employment;

OECD (2001) Business Views on Red Tape: Administrative and Regulatory Burdens on Small and Medium-sized Enterprises'.

European Commission (May 2007) Models to Reduce the Disproportionate Regulatory Burden on SMEs. Report of the Expert Group;

Chittenden, F. et al (2002) Regulatory burdens of small business: a literature review;

COM(2007) 592 Small and medium-sized enterprises - Key for delivering more growth and jobs: a mid-term review of Modern SME policy;

COM(2007) 581 The European Interest: Succeeding in the age of globalisation. Contribution of the Commission to the October Meeting of Heads of State and Government;

Com (2006) 691 Measuring administrative costs and reducing administrative burdens in the European Union;

Department for Business, Enterprise and Regulatory Reform (2008) 25 ideas for simplifying EU law;

EPEC (2006) Impact assessment for improving SME specific research schemes and measures to promote SME participation in the framework programme.

## ANNEX 5: LIST OF LEGISLATION MENTIONED BY STAKEHOLDERS

The following pieces of legislation were mentioned by stakeholders as specifically problematic for SMEs:

- § Regulation (EC) 530/1999 Statistical survey on the cost of labour, on the structures of workers in enterprises.
- § Directive 91/533/EC relating to the obligation of the employer to inform the worker of the conditions applicable to the contract or employment relationship
- § Directive 2002/73/EC modifying directive 76/207/EC relating to the implementation of the principle of equal treatment between men and women
- § Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (artificial optical radiation) (19th individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- § Directive 92/57/EC on the implementation of minimum safety and health requirements at temporary or mobile construction sites.
- § Directive 2006/12/EC
- § Directive 2002/96/EC of 27 January on waste electrical and electronic equipment (WEEE)
- § Regulation (EC) N° 761/2001 of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)
- § Directive 94/62/EC of 20/12/94 on packaging and packaging waste
- § Directive on environmental liability 2004/35/EC
- § Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and restriction of chemicals (REACH)
- § Directive 94/35/EC Sweeteners for use in Foodstuffs;
- § Directive 95/2/EG on food additives other than colors and sweeteners;
- § Labeling Directive 2000/13 including Declaration of Allergens;
- § Directive 89/108/EWG on food additives;
- § Directive 90/496/EEC on nutrition labeling;
- § Directive 1829/2003 on GMO definitions;
- § Directive 1830/2003 on GMO labeling;
- § Regulation 258/197 concerning novel foods and novel food ingredients;
- § Hygiene regulations 852/2004, 853/2004
- § Directive 95/46 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

- § Directive 98/6/EC of the European Parliament and the Council of 16 February 1998 on consumer protection in the indication of the prices of products offered to consumers.
- § Regulation 638/2004/EC on Community statistics relating to the trading of goods between Member States.
- § Council Directive 92/12/EEC of 25 February 1992 on the general arrangements for products subject to excise duty and on the holding, movement and monitoring of such products
- § Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs
- § Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market
- § Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations