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# COMMISSION STAFF WORKING DOCUMENT

Action Programme for Reducing Administrative Burdens in the EU Final Report

Accompanying the document

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions

**EU Regulatory Fitness** 

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## **EXECUTIVE SUMMARY**

Reducing administrative burdens so as to improve the business environment in the EU has been a high priority for the European Commission in recent years. The Action Programme for Reducing Administrative Burdens on business stemming from EU legislation by 25% was launched by the Commission and endorsed by the Council in 2007<sup>1</sup>.

The aim of the ABR Action Programme was to measure costs<sup>2</sup> imposed by information obligations on businesses and to eliminate any unnecessary administrative burdens in thirteen selected priority areas. Under this programme, measures worth EUR 30.8 billion in annual savings for businesses have been adopted at EU level. This represents a 25% reduction in existing administrative burdens stemming from EU legislation, which have been estimated at EUR 123.8 billion. Another 5.5% of burden reduction, which would take the total to 30.5%, could be achieved if the additional measures already proposed by the Commission were adopted by the European Parliament and the Council. It has been estimated that in the medium term the programme could lead to an increase of 1.4% in EU GDP, equivalent to EUR 150 billion.

The process has also given rise to a change in administrative culture, establishing a priority focus on achieving public-policy objectives in the least burdensome way for business and citizens.

This final report presents the results achieved in the Action Programme.

Concerning the achievements of the programme itself, the legislative changes adopted at EU level will yield their full impact only if they are implemented in Member States without undue delay and in the most efficient and least burdensome way. Continued collaboration and sustained effort at all levels of government are needed to ensure that the EU measures are implemented so as to produce the greatest benefits at least costs.

The search for further possible reductions in reporting requirements will continue so as to achieve a broader and deeper overall reduction in the regulatory burden at EU level, as detailed in the Communication on 'EU Regulatory Fitness'.

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<sup>&</sup>lt;sup>1</sup> COM(2007) 23 "' Action Programme for Reducing Administrative Burdens in the European Union'"

<sup>&</sup>lt;sup>2</sup> <u>COM(2006) 691</u>: 'Measuring administrative costs and reducing administrative burdens in the European Union'-accompanying the Strategic Review of Better Regulation in the EU.

# Action Programme for Reducing Administrative Burdens in the EU Sectoral Reduction Plans. Final Report

## 1. BACKGROUND

Following the first strategic review of the Better Regulation initiative in November 2006, the Commission proposed an ambitious joint strategy with the Member States to reduce the administrative burden on business stemming from EU legislation by 25% by 2012.<sup>3</sup> The proposal was part of the efforts to generate growth and jobs in Europe.

The Action Programme for Reducing Administrative Burdens in the European Union<sup>4</sup> was launched by the Commission in January 2007 and endorsed by the European Council in March of the same year. The Council simultaneously invited Member States 'to set national targets of comparable ambition'.

The aim of the Action Programme was to measure costs imposed by information obligations on business and to eliminate unnecessary administrative burdens in order to improve the efficiency of legislation without jeopardising its purpose.

The programme covered both EU legislation and national legislation implementing and transposing EU law. The scope of the programme initially included 42 legislative acts which were later extended by a further 30 acts<sup>5</sup> in 13 Priority Areas identified as the most burdensome for businesses.

In 2007 a measurement exercise was performed in all 27 Member States to estimate the existing level of administrative burden. This baseline measurement identified the extent of existing administrative burden and provided a basis for the subsequent calculation of the reduction measures. The Commission hired a consortium of consultants to assist in this exercise using the so-called 'EU Standard Cost Model' inspired by different variants of the Standard Cost Model (SCM)<sup>7</sup> used in a number of Member States.

Member States' contribution to the exercise was mainly channelled through the High Level Group of National Experts on Better Regulation and the Single Points of Contact designated in each Member State to coordinate the national feedback on the Action Programme.

<sup>4</sup> COM(2007) 23 'Action Programme for Reducing Administrative Burdens in the European Union '.

<sup>&</sup>lt;sup>3</sup> COM(2006) 689 'A strategic review of better regulation in the European Union '.

<sup>&</sup>lt;sup>5</sup> COM(2009) 16 'Reducing Administrative Burdens in the European Union'. Annex to the 3<sup>rd</sup> Strategic Review on 'Better Regulation' in the European Union.

<sup>&</sup>lt;sup>6</sup> COM(2005) 518 'EU common methodology for assessing administrative costs imposed by legislation' and SEC(2005) 1329; Annex Outline of the proposed EU common methodology and Report on the Pilot Phase (April– September 2005).

<sup>&</sup>lt;sup>7</sup> 'The SCM approach does not aim at producing statistically valid results, but rather expert-based estimates that help in understanding the nature of the problem and assessing reduction progress in relative terms.' COM(2009) 16 Commission working Document. Reducing Administrative Burdens in the European Union — Annex to the 3<sup>rd</sup> Strategic Review on Better Regulation.

Stakeholders' involvement was structured around three pillars: the work of the High Level Group of Independent Stakeholders on Administrative Burdens established in 2007<sup>8</sup> to advise the Commission on the implementation of the programme; extensive consultation to give businesses the possibility to voice their concerns and make concrete suggestions which was supported by an online tool; and the organisation of local workshops and seminars.

The findings of this measurement exercise were presented in the Communication of 22 October 2009<sup>11</sup> together with concrete sectoral reduction plans that would contribute to achieving the overall target. Two so-called 'Fast-track' packages of measures to help achieve the reduction target had already been presented in 2007 and 2008.

The sectoral reduction plans included burden estimates and defined specific actions to be taken in each of the 13 Priority Areas listed in the Programme: Agriculture and Agricultural Subsidies; Annual Accounts / Company Law; Cohesion Policy; Environment; Financial Services; Fisheries; Food Safety; Pharmaceutical Legislation; Public Procurement; Statistics; Taxation and Customs; Transport; Working Environment / Employment Relations.

The administrative burdens on business at the beginning of the Commission's term of office (2005) were estimated at EUR 123.8 billion. A 25% reduction would thus amount to cutting the burden on businesses by around EUR 40 billion.

Following the 2009 Communication, the Commission has published<sup>12</sup> regular updates on how much the administrative burden has been reduced by the measures included in the sectoral reduction plans.

## 2. OVERVIEW OF THE FINAL RESULTS

The final results of the programme show that the 25% reduction target was duly achieved. The Commission has tabled proposals with an administrative burden reduction potential of EUR 40.9 billion. Some of this potential (roughly EUR 3.2 billion) was lost in the legislative process with the European Parliament and Council, the overall reduction is then estimated at

The members of the Group include the leaders of several bodies overseeing programmes to cut red tape in the Member States, as well as representatives from industry, small and medium-sized enterprises and environmental and consumer organisations and social partners.

<sup>&</sup>lt;sup>8</sup> Commission Decision of 31 August 2007 setting up the High Level Group of Independent Stakeholders on Administrative Burdens — C(2007)4063.

<sup>&</sup>lt;sup>9</sup> In 2010, the group chaired by Dr Edmund Stoiber saw its mandate in relation to the Programme extended until 2012. In November 2011, the HLG adopted a report: 'Europe can do better: Report on best practice in Member States to implement EU legislation in the least burdensome way', a report providing concrete examples of best practice proposed primarily by Member States themselves.

<sup>&</sup>lt;sup>10</sup> Businesses were consulted in numerous occasions. More than 3000 interviews of business stakeholders were conducted to spot unnecessary burdens and possible solutions, and additional public consultations were carried out for the sectoral reduction measures.

<sup>&</sup>lt;sup>11</sup> COM(2009) 544 'Action Programme for Reducing Administrative Burdens in the EU. Sectoral Reduction Plans and 2009 Actions'.

<sup>12</sup> http://ec.europa.eu/dgs/secretariat general/admin burden/result burden/result burden en.htm

EUR 37.6 billion (30.5% of the total estimated burden). Measures worth EUR 30.8 billion with a reduction potential of 25% have already been adopted by the European Parliament and the Council. However, some of them still need to be implemented in the Member States.

Reducing administrative burdens is a dynamic process and the Action Programme could still generate additional savings for businesses worth EUR 6.8 billion (5.5%) if the measures already proposed by the Commission were adopted by the European Parliament and Council in a way that their full burden-reduction potential remains untouched.

Table 1 provides an overview of the overall results of the Action Programme. It indicates the estimated burden reduction contained in the measures originally proposed by the Commission in each priority area and the reduction resulting from the measures as adopted by the Parliament and the Council. The last column presents the estimated total reduction in administrative burden to be achieved by the measures already adopted or proposed by the Commission. <sup>13</sup>

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<sup>&</sup>lt;sup>13</sup> The Annex presents detailed results achieved by the measures contained in each sectoral reduction plan.

Table 1

Priority Area	Proposed by the Commission	A Adopted/ Completed	B Pending adoption by co- legislator	D=A+B Total reduction potential
Agriculture / Agricultural Subsidies	-1891.4	-1891.4	-	-1891.4
2. Annual Accounts / Company Law	-10043.5	-4931.3	- 1700	-6631.3
3. Cohesion Policy	-234.9	- 179.9	-55.0	- 234.9
4. Environment	-302.7	- 302.7	-	- 302.7
5. Financial Services	+29.5	- 141.5	+171	+29.5
6. Fisheries	-33.4	- 25.9	-	-25.9
7. Food Safety	+78.8	+79.2	-0.4	+78.8
8. Pharmaceutical Legislation	-101.1	- 101.1	-267.4	- 368.5
9. Public Procurement	-216.6	- 60.1	-156.5	-216.6
10. Statistics	-329.6	- 329.6	-	- 329.6
11. Taxation/Customs	-26334.3	- 21 936.9	- 4397.4	- 26334.3
12. Transport	-1 263.3	- 748.3	- 415	- 1163.3
13. Working Environment /Employment Relations	-232.5	- 232.5	-	- 232.5
(million Euro)	-40 875	-30802	-6820.7	-37 622.7
% of the total AB estimated (123760.8)	33	25	5.5	30.5

## 2.1. MEASURES ADOPTED

The sectoral reduction plans include more than 120 measures to reduce the administrative burden affecting the 13 priority areas. Measures adopted include more than 40 changes introduced through regulations and 26 through directives. Additional reductions have been achieved through 15 measures of a non-legislative nature

The biggest reductions have taken place in 3 policy areas: Agriculture, Annual Accounts / Company Law and Taxation / Customs, with potential reductions worth EUR 28.7 billion (23% of the initially estimated burden), reflecting the fact that these three areas accounted for more than 80% of the administrative burden initially estimated.

Reducing inspection costs stemming from marketing standards for fruits and vegetables (part of Regulation (EC) No 1234/2007 — Single Common Market Organisation Regulation) alone amounted to a potential burden reduction of EUR 973.7 million.

Additionally, the measure allowing Member States to exempt micro-enterprises from accounting directives (part of Directive 2012/6/EU of 14 March 2012) presented potential savings of close to EUR 3.5 billion. Although high, this savings potential is substantially lower than that proposed by the Commission (EUR 6.3 billion).

In the area of Taxation and Customs, the measure to foster equal treatment between paper and e-invoices to enable wider use of electronic invoicing (part of Directive 2010/45/EU amending Directive 2006/112/EC on the common system of value added tax as regards the rules on invoicing) produced a burden reduction potential of EUR 18.8 billion. The measures to modernise customs procedure and especially to switch to a fully electronic customs procedure (Regulation (EC) No 450/2008 laying down the Community Customs Code (Modernised Customs Code and Decision 70/2008/EC on a paperless environment for custom and trade) while not being still in application, are expected to produce a burden-reduction of EUR 2.43 billion.

## 2.2. MEASURES PROPOSED

Among the measures proposed by the Commission which are still pending before the European Parliament and Council, the economically most significant reductions are also expected within the areas of Annual Accounts/Company Law and Taxation and Customs.

Among these reduction measures is the proposal to modernise EU accounting directives through a general overhaul<sup>14</sup> which could deliver annual savings worth EUR 1.7 billion.

The Commission 2004 proposal setting up a One Stop Shop and increasing thresholds for the use of special schemes for SMEs and distance sales of goods, <sup>15</sup> with potential savings worth

<sup>&</sup>lt;sup>14</sup> COM(2011) 684 Proposal for a directive of the European Parliament and the Council on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings.

<sup>&</sup>lt;sup>15</sup> COM(2004) 728 Proposal for a Council directive amending Directive 77/388/EEC with a view to simplifying value added tax obligations, Proposal for a Council directive laying down detailed rules for the refund of value added tax, provided for in Directive 77/388/EEC, to taxable persons not established in the territory of the country but established in another Member State, Proposal for a Council regulation amending Regulation (EC) No

EUR 4.4 billion, is still pending in the Council. Nonetheless, an important first step has been taken to address the complexity of the EU VAT system for businesses. Member States have given their agreement to the setting up of a mini-One Stop Shop for cross border sales to private individuals of telecoms, broadcasting and e-services which will enter into force on January 2015. It is an extension of the e-commerce scheme which exists since 2003 for non-EU suppliers of e-services that allows the submission of a single VAT declaration and payment via an electronic portal with the payment allocated automatically to the different Member States where VAT is due on the basis of the information supplied. The mini-One Stop Shop will reduce significantly the burdens imposed on business and could be extended to other types of transactions thereafter, as was mentioned in the Communication on the future of VAT<sup>16</sup>.

The two measures, modernisation of the accounting directives and the proposal setting up a One Stop Shop system, in themselves would account for a further reduction of 5% of the administrative burden initially estimated.

#### 3. CONCLUSIONS

The Action Programme has delivered on the Commission's commitment to reduce administrative burdens for business stemming from EU legislation by 25 % by 2012. Part of its success is due to the strong support from all EU institutions at the highest political level.

Moreover, the Commission had pointed out from the beginning that the 25 % reduction target was a joint objective which could only be attained on the basis of shared responsibility and common endeavour on the part of the Member States and the European Institutions. Following the European Council's invitation to Member States to adopt targets of similar ambition, all Member States adopted similar targets to reduce administrative burdens at national level. The next few years will show whether these commitments have been met and EU proposals implemented at national level, so that the businesses can feel the difference 'on the ground'.

The programme has also served as an important driver for a change in the culture of EU administration so that the impact of legislation on administrative burdens and thus on businesses is taken into account from the beginning.

However, concerns have been raised in various quarters regarding elements of the programme, including:

- the programme's exclusive focus on administrative burdens, not taking into account other costs and benefits that must be assessed to achieve a full picture of the efficiency and effectiveness of legislation; and
- the extent of resources deployed in measuring the baseline level of administrative burdens and on maintaining an overview of the progress of the programme.

1798/2003 as regards the introduction of administrative cooperation arrangements in the context of the one-stop scheme and the refund procedure for value added tax.

<sup>&</sup>lt;sup>16</sup> COM(2011) 851 final

Another key issue relates to the shared responsibility of the European Institutions and Member States. There have been specific cases where the Commission had identified and proposed suitable measures to simplify and to reduce the administrative burdens on business, but where the measures adopted by the European Parliament and the Council offered less scope administrative burden reduction. In addition, EU legislation needs to be implemented in Member States; the benefits of the programme cannot be achieved unless measures adopted at EU level are implemented in Member States by the competent authorities in the most efficient and least burdensome way.

The Commission is determined to go further and remove not only administrative but any unnecessary regulatory burden within the integrated approach explained in the Communication on 'EU Regulatory Fitness'. The Regulatory Fitness and Performance Programme (REFIT)which seeks to reduce the regulatory burden and to ensure the body of EU legislation remains fit for purpose will take Smart Regulation to the next level. It will include a follow-on programme called ABR-Plus which will focus on the implementation in the Member States of the measures adopted at EU level under the ABR Action Programme.

## **ANNEX**

# SECTORAL PLANS FOR REDUCING ADMINISTRATIVE BURDENS (2012) — RESULTS 2012

They report the estimated changes in the level of administrative burden for each of the measures included in the sectoral reduction plans. The presentation follows the order used in Communication COM(2009) 544, where detailed explanations for each of the measures, estimations and the correspondence between the measures listed in the sectoral reduction plans and the legal acts in scope of the Action Programme can be found. The 'change in the level of AB' indicates the final consolidated impact of the measure, including changes introduced by other EU institutions as the case may be. The total figures for each sectoral plan refer to the maximum estimated potential of the measures, assuming that gold plating is not introduced at the national level (they do not include changes resulting from factors other than those specified in the tables). Estimations were based on background studies or impact assessments carried out by the Commission between 2007 and 2012.

The measures are listed as 'adopted' and 'proposed'.

Measures adopted at EU level include adoption of legal acts by Parliament and the Council and executive acts adopted by the Commission, as well as some measures of a non-legislative nature. Where the measure adopted is legislative and it is addressed only to the EU level, the dates of the entry into force and application are indicated. The deadline for transposition into national law is stated where the legal act requires joint action by the EU and the Member States. Measures of this type are highlighted in green.

Proposed measures (e.g. Commission legislative proposals pending adoption by the Council and Parliament) are highlighted in blue and indicate the date of adoption by the Commission.

<sup>&</sup>lt;sup>17</sup> Communication from the Commission to the European Parliament and the Council on the Action Programme for Reducing Administrative Burdens in the Sectoral Reduction Plans and 2009.

<sup>&</sup>lt;sup>18</sup> 'gold plating' by Member States is defined in COM(2005) 97 Better Regulation for Growth and Jobs in the European Union as '...the introduction of requirements or procedures in the course of the transposition of EU legislation which are not required by that legislation '.

## 1. AGRICULTURE

The priority area Agriculture and Agricultural Subsidies is the third-biggest priority area in terms of administrative burdens imposed on businesses. The lion's share of that burden (EUR 3.81 billion) stems from Council Regulation (EC) No 1782/2003 (now Council Regulation (EC) No 73/2009) establishing common rules for direct support schemes and certain support schemes for farmers (also known as the Single Payment Scheme).

The so-called 'Health Check' reform simplified formalities for farmers benefiting from the Single Payment Scheme and reduced administrative burdens for business by an estimated EUR 250 million. For instance, further decoupling of direct payments was introduced by removing the link between the receipt of a direct payment and the production of a *specific* product. This gave farmers greater freedom to produce according to market demand. Decoupling also means that farmers no longer need to provide information on specific crops (before the reform there were more than 3 million crop specific applications annually, among which almost 800,000 applications for energy crops).

The highest burden reduction, estimated at more than EUR 970 million, was achieved when the Commission adopted Regulation (EC) No 1221/2008 reducing the number of products subject to specific marketing standards for fruit and vegetables from 36 to 10: labelling-class details were no longer required for 26 products representing 25% of the trade in fresh fruits and vegetables. The regulation also rationalised the associated checking operations, introducing risk-based controls, and established a general marketing standard covering most fruit and vegetables. Another major change with estimated savings of more than EUR 606 million was the simplification of egg-labelling requirements. This greater flexibility reduces costs not only for farmers but also for the downstream sector, as well as control costs for Member States. By exempting producers with up to 50 laying hens, more than 5 million farms producing more than 100 billion eggs can be exempted from marking eggs with the producer code.

At the other end of the spectrum, Commission Regulation (EC) No 1291/2000 (now Commission Regulation (EC) No 376/2008) laying down rules for the system of import and export licences was often considered a major irritant even if it meant only EUR 12 million in administrative burdens. The number of products requiring an import or export licence has now been reduced from over 500 to 65 for imports and 43 for exports.

Most of the measures reducing administrative burdens were adopted at an early stage in the Action Programme (between 2007 and 2009), leading to estimated savings of about EUR 1.9 billion.

Agriculture	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
1. Simplifying formalities for farmers benefiting from the 'Single Payment Scheme' (part of the 'Health Check')	-250.0	Adopted Council Regulation (EC) No 73/2009 of 19 January 2009	E: 1.02.2009 A: 1.01.2009
2. Reducing farmers' book-keeping and inspection costs stemming from 'cross-compliance' obligations	-5.5	Adopted Commission Regulation (EC) No 1550/2007 of 20 December 2007 amending Regulation (EC) No 796/2004	E: 24.12.2007 A: 1.01.2008
3. Reducing the number of agricultural products for which a licence is necessary	-6.0	Adopted Commission Regulation (EC) No 514/2008 of 9 June 2008 amending Regulation (EC) No 376/2008	E: 13.06.2008: A: for 1.07, 1.08, 1.09 and 1.10 = 2008
4. Simplifying egg labelling	-606.7	Adopted Commission Regulation (EC) No 557/2007 of 23 May 2007	E: 31.05.2007 A: 1.07.2007
5. Reducing inspection costs stemming from marketing standards for fruit and vegetables	-973.7	Adopted Commission Regulation (EC) No 1221/2008 of 5 December 2008 amending Regulation (EC) No 1580/2007	E: 16.12.2008 A: 1.07.2009
6. Suppressing administrative burdens linked to special support schemes (part of the 'Health Check')	-28.0 (it also concerns item 12)	Adopted Council Regulation (EC) No 1234/2007 of 22 October 2007; Council Regulation (EC) No 72/2009 of 19 Jan 2009	E: 23.11.2007 A: 1.12.2008 with exceptions
7. Reducing information obligations for payments to farmers by abolishing the '10-month' rule	-21.5	Adopted Council Regulation (EC) No 146/2008 of 14 February 2008	E: 28.02.2008 A: 1.01.2008
8. Repealing legal requirements on registration of contracts in the hops sector	n/a	Proposed COM(2011) 626 final/2 of 19.10.2011	
9. Simplifying controls on farmers by striving for appropriate control rates	n/a	Working Documents DS/2009/27 and DS/2009/28; cf. also Measure 13 below	A: 1.01.2010
10. Increasing the tolerable risk of errors for funds used in rural development	n/a	Preparation completed. Communication COM(2010) 261 final; SEC(2010) 640; SEC(2010) 641	
11. Concentrating cross-compliance rules in one legal instrument	n/a	Proposed COM(2011) 628 final/2 of 19.10.2011	
12. Reducing control frequency related to dried fodder (EUR 16.2 m reduction included in No 6 above)	Change included in item 6.	Adopted Council Regulation (EC) No 72/2009 of 19 January 2009 amending Regulation (EC) No 1234/2007 The support scheme for dried fodder will end in 2012	E: 3.02.2009 A: 1.04.2012
13. Simplifying measures implementing the Single Payment Scheme for farmers, including cross-compliance, modulation and the integrated administration and control system	n/a	Proposed and partially adopted Initially COM(2010) 537/539, now included in Commission Proposal for Council Regulation COM(2011) 625, amended by COM(2012) 552 final. Cf. Commission Regulation (EC) No 146/2010; Commission Regulations No 1122/2009; No 1120/2009; DS/2009/27; DS/2009/28	E: 1.03.2010

Sectoral total	-1891.4		
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## 2. ANNUAL ACCOUNTS

The Commission has proposed measures worth more than EUR 10 billion and measures so far adopted by the co-legislator have achieved a potential administrative-burden reduction for EU business of EUR 4.9 billion.

The final adoption in spring 2012 of the Commission proposal on allowing micro-enterprises to be exempted from accounting directives was an important step in achieving the Action Programme's 25% reduction target, although savings will be substantially lower than initially estimated. The original Commission proposal for an outright exemption for micro-entities from all EU accounting requirements included potential savings estimated at around EUR 6.3 billion. However, the amendments introduced by the Parliament and Council during the legislative process (retaining minimal accounting requirements for micro-entities and thus affecting fewer companies than originally anticipated) reduced the potential savings to EUR 3.4 billion. It is also regrettable that the proposal COM(2008) 194 of 17 April 2008 to simplify obligations concerning the publication and translation of financial information — which could have led to savings of EUR 660 million — was finally withdrawn by the Commission due to lack of agreement in the Council.

The losses might nonetheless be outweighed by the proposal modernizing EU accounting directives through a general overhaul, which aims, in particular, to create a new simple and harmonised regime for small companies and entails savings worth EUR 1.7 billion. Whether this potential will be fully realised depends on the negotiations in the Council and Parliament. It is also worth noting that the recently adopted Directive on the interconnection of central, commercial and companies' registers will lead to a reduction of EUR 69 million in addition to the savings presented in the sectoral plan in 2009.

Annual Accounts / Company Law	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Allowing more small and medium-sized companies to benefit from simplified accounting/auditing regimes	- 862.6	Adopted Directive 2006/46/EC of 14 June 2006	E: 5.09.2006 T: 5.09.2008
Limiting the amount of information in the notes to the accounts for medium-sized enterprises.  Clarifying that consolidated accounts are not required if all subsidiaries are non-material	- 8.2	Adopted Directive 2009/49/EC of 18 June 2009	E: 20.08.2009 T: 1.01.2011
Allowing Member States to exempt micro-enterprises from accounting directives	-3 499.4	Adopted Directive 2012/6/EU of 14 March 2012 (burden reduction of the original Commission proposal was — €6 300.0 million)	simplifications under the new Directive are only optional, no transposition period for MS is required
Modernising EU accounting directives through a general overhaul	-1 700.0	Proposed COM(2011) 684 of 25 October 2011	
Simplifying the obligations related to changes to the capital of public limited liability companies	- 150.0	Adopted Directive 2006/68/EC of 6 September 2006	E: 15.10.2006 T: 15.04.2008
Abolishing the obligation to provide an independent expert's report on merger or division in case of waiver	- 170.1	Adopted Directive 2007/63/EC of 13 November 2007	E: 7.12.2007 T: 31.12.2008
Simplifying the reporting requirements in case of a merger or division	- 172.0	Adopted Directive 2009/109/EC of 16 September 2009	E: 22.10.2009 T: 30.06.2011
Interconnection of business registers	- 69.0	Adopted Directive 2012/17/EU of 13 June 2012	E: 20.07 2012 T: 7.07.2014, special provisions affect implementing acts referred to in Art. 4c of Directive 2009/101/EC
Sectoral Total	-6631.3		

#### 3. COHESION POLICY

Cohesion Policy is a special priority area where the measurement of administrative costs was not limited to businesses. Implementation of the Cohesion Policy is multilayered, involving national, regional and local authorities; its beneficiaries are also public and semi-public authorities and non-profit organisations.

Estimated burdens stemming from EU legislation for the 2007-2013 funding period, calculated on the basis of the previous period, amounted to EUR 929 million. Following the economic and financial crisis, the framework established for cohesion policy for the programming period 2007-2013 was simplified to make implementation of the programmes easier and to boost absorption of the funds. The amendments to the general provisions and implementing rules adopted under the Action Programme for the period 2007-20013 simplify reimbursement calculations, reduce the work load and control burden on beneficiaries and lighten reporting in terms of information obligations. At several meetings with the stakeholders, those responsible for actually implementing the measures expressed considerable appreciation for these two measures and for the simplification package in general. In addition to the legislative measures during 2008 and 2009, the Commission has provided extensive guidance through the management committees and regular technical meetings of audit authorities and has organised large-scale training and sectoral events for Member States.

A study of the feasibility of developing national-level central clearing houses for Cohesion Policy reporting was completed and has served as the basis for introducing in COM(2011) 615 a requirement for the financing period 2014-2020 (CPR) to set up a system by the end of 2014 enabling all exchanges of information between the beneficiary and the national/regional authorities to take place by way of electronic information exchange, without a duplicating paper trail and supplying all information only once. The Council, however, has expressed a wish to postpone the deadline from 2014 to 2016, potentially postponing some of the benefits this proposal would offer to beneficiaries.

It is worth noting that in addition to the simplification and burden-reduction achieved under the Action Programme, the Commission has proposed for the period 2014-2020 a legislative framework which aims to further simplify the management of EU Funds under cohesion policy. The results of a study undertaken by the Commission on the impact of regulatory changes proposed for the period 2014-2020 on the

Council Regulation (EC) No 1083/2006 laying down general provisions on the European Regional Development Fund, the European Social Fund and the Cohesion Fund repealing the single legal act in scope of the Action Programme, Council Regulation (EC) No 1260/1999.

administrative burden of beneficiaries of the ERDF and the Cohesion Fund<sup>20</sup> indicate, with regard to the baseline established for the period 2007-2013,<sup>21</sup> that:

- the Commission's proposal for a shift to 'e-cohesion' would reduce the aggregate administrative burden at EU level by approximately 11%.<sup>22</sup> This requirement is based on the main recommendation of the High Level Group of Independent Stakeholders on Administrative Burdens stemming from the initial assessment of administrative burden in the period 2000-2006.
- the estimated potential burden reduction of the remaining modifications proposed by the Commission, if implemented in full by Member States, is 9%.<sup>23</sup> These include rules allowing for a simpler use of flat rates, unit costs and lump sums, harmonisation of eligibility rules applied under shared management and annual closure leading to a shorter period for the retention of documents and audit.
- in the context of shared management, the Commission and the Member States share responsibility for simplification and administrative-burden reduction. The Commission has therefore also proposed that Member States undertake an assessment of administrative burdens stemming from national procedures and practices and set out in their Partnership Contract and programmes for the period 2014-2020 actions to reduce this burden. This requirement is expected to contribute to a further reduction of the administrative burden on beneficiaries.

<sup>&</sup>lt;sup>20</sup> 'Measuring the impact of changing regulatory requirements to administrative cost and administrative burden of managing EU structural funds (ERDF and Cohesion Fund)', to be finalised in 2012. The study does not cover the European Social Fund and since the interventions financed are different from those supported under the ERDF and the Cohesion Funds, the results should not be extrapolated to this instrument.

See 'EU project on baseline measurement and reduction of administrative costs' 5 March 2009 <a href="http://ec.europa.eu/enterprise/policies/smart-regulation/documents/ab\_studies\_2009\_en.htm#h2-3">http://ec.europa.eu/enterprise/policies/smart-regulation/documents/ab\_studies\_2009\_en.htm#h2-3</a>. This assessment also covered the European Social Fund; accordingly, a direct comparison of results is not possible.

Referred to the baseline established for the period 2007-2013.

Referred to the baseline established for the period 2007-2013.

Cohesion Policy	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Reducing administrative burdens for projects (co)financed by EU Structural Funds regarded as revenue-generating	- 18.4	Adopted Council Regulation (EC) No 1341/2008 of 18 December 2008	E: 25.12.2008 A: 1.08.2006
Simplifying the management and control of operations co-financed by the ESF and the ERDF	- 45.8	Adopted Regulation (EC) No 396/2009 of 6 May 2009 and Regulation (EC) No 397/2009 of 6 May 2009	396/2009 E: 22.05.2009 A: 1.08.2006 397/2009 E: 11.06.2009 A: 1.08.2006
Simplifying and clarifying general provisions on the ERDF, ESF and the Cohesion Fund	- 33.4	Adopted Commission Regulation (EC) No 846/2009 of 1 September 2009	E: 14.10.2009 A (exception): 16.01.2007
Providing guidance and training on control and audits of Structural Funds	- 20.0	Adopted.  Guidance notes (on annual control reports and opinions; on reliance on the work of other auditors; on management verifications on certification; on partial closure; on revenue generating projects; and on fraud indicators)	
Facilitating, simplifying and clarifying certain general provisions on the ERDF, ESF and the Cohesion Fund	- 62.3	Adopted Regulation (EU) No 539/2010 of 16 June 2010	E: 25.06.2010 A (exceptions): 1.08.2006 1.01.2007 10.06.2009
Developing, at national/regional level, central clearing houses for Cohesion Policy reporting	- 55.0	Proposed Commission Proposal COM(2012)496 final for 2014-2020 (CPR)	
Sectoral Total	- 234.9		

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## 4. ENVIRONMENT

The administrative burden stemming from the seven acts in scope within the priority area Environment was estimated at EUR 1.2 billion, which amounts to only one percentage point of the estimated total administrative burden. This figure is relatively low in comparison with the perception by businesses; this is partly due to confusion with compliance costs in the environmental area and to the high visibility of certain requirements.

Often Member States incur different costs for doing the same thing — around one third of the administrative burden is estimated to be the result of inefficient public and private administrative practices, meaning there is further scope for sharing good practice. A recent study<sup>24</sup>, pointed to relevant other issues. For example, the flexible implementation allowed in several directives has resulted in higher overall administrative costs. Uneven implementation implies different administrative requirements for companies operating across the EU in terms of labelling, monitoring, reporting, notification, permits, etc. As a result, companies operating in different Member States need to run different systems and so incur additional costs. Such costs are very hard to quantify but, could amount to a few million euros per year. This could be particularly relevant for SMEs, where such administrative costs could be a barrier to exporting to other Member States.

To date, the Commission has taken action to address eight out of the eleven measures included in the Action Programme. Three other measures fall under the responsibility of the Member States and it is assumed for the purposes of this report that they have also taken the necessary steps to ensure that the required measures are introduced and the administrative burdens removed/reduced. In most instances, the deadline for transposition or application has not yet been reached; it is therefore not yet possible to measure the actual reductions achieved. The figures in the table are accordingly the figures presented in the 2009 Communication.

The newly adopted directive 2012/19/EU (Waste electrical and electronic equipment) is expected to cut unnecessary burdens for producers of such equipment by harmonising the registration format and certain reporting requirements. This will allow the integration of horizontal reporting between MS and integration of vertical reporting chains. The new directive also requires cooperation between administrations and MS must ensure that multiple payments are reimbursed. Proportionally, SMEs are presumed to benefit the most.

Concerning biocidal products, the Commission proposal introduced simplified, more effective and efficient legislation, reducing unnecessary burdens for Member States and industry whilst maintaining a high level of protection of human health and the environment. Significant savings to business will be achieved through obligatory sharing of data from tests involving vertebrate animals at the substance-evaluation and product-authorisation stage. SMEs in particular will benefit from the partial harmonisation of the fee structure.

The costs of not implementing the environmental *acquis*, published in September 2011.

Directives 2010/75/EU on industrial emissions (IED) and 2012/18/EU on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EU (Seveso) will ensure improved coordination of inspections between the two regimes. Recital 26 of Seveso makes clear that 'Where possible, inspection should be coordinated with those under other Union legislation, including Directive 2010/75/EU on industrial emissions, where appropriate'. Furthermore, Article 23(3) of the IED includes scope for inspection plans to introduce provisions on cooperation between different inspection authorities.

Directive 2010/75/EU on industrial emissions (IED) provides greater clarity with regard to the reconsideration and updating of permits. The Directive requires reconsideration and updating of the permit conditions by the competent authority, not the renewal of permits. Most permit reconsideration and updating will take place as a result of the publication of the best available techniques (BAT) conclusions under the IED, which are published eevery eight years. The reconsideration and updating will likely have the same frequency.

Environment	Change in the level of AB	State of play	Entry in force (E) Application (A) Transposition (T)
Simplifying procedures for controlling waste shipments	- 3.6	Adopted Regulation EU No 1013/2006 of 14 June 2006 on Shipments of Waste	E: 17.06.2006 A: 12.07.2007
Simplifying the regime for integrated pollution prevention and control	- 32.0	Adopted Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)	E: 6.01.2011 T: 7.01.2013
Harmonise national information obligations on waste electrical/electronic equipment and ensure register interoperability	- 66.0	Adopted Directive 2012/19/EU,on waste electrical and electronic equipment OJ L 197, 24.7.2012, p. 38–71	E: 13.08. 2012 T: 14. 02. 2014
Streamlining reporting obligations on substances depleting the ozone layer	- 0.5	Adopted Regulation (EC) No 1005/2009 of 16 September 2009	E: 20.11.2009 A: 1.01.2010
Simplifying authorisation procedures for the placing of biocidal products on the market	-140.0	Adopted. Regulation (EU) N 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (replacing Directive 98/8/EC)	E:17.07.2012 A: 1.09. 2013
Setting up a website for submitting and changing notifications of presence or changes of dangerous substances	- 1.5	The notification procedure is handled by Member States	
Improving coordination between IPPC and Seveso inspections by national authorities (legislative proposal)	- 1.1	7: Adopted Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)	E: 6.01.2011 T: 7.01.2013
Improving coordination between IPPC and Seveso inspections by national authorities (implementing provisions)		8: Adopted. Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC	E: 13.08.2013 T: 31.05.2015
Encouraging Member States to update IPPC permits rather than demand their renewal	- 5.0	Adopted. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)	E: 6.01.2011 T: 7.01.2013
Simplifying and streamlining the notification system for shipments of waste	- 44.0	The Commission recommended that MS introduce such a system by letter to the Perm Reps in July 2010.	
Introducing online systems through which treatment facilities can issue vehicle-destruction certificates	- 9.0	The Commission recommended that MS set up an IT system, as this is a matter for implementation by MS.	
Sectoral Total	302.7		

#### 5. FINANCIAL SERVICES

Financial Services have been a focal point of the financial crises; filling in the gaps in financial-sector regulation and strengthening the supervision of the financial sector in Europe have been key aspects of stabilising the financial markets. The increasing regulation of the financial services has in some cases led to increases in administrative burdens in this sector as the focus has been on additional supervision and increased transparency, so as to increase market confidence. Such increases are only partly reflected in the final results of the programme, as measures taken refer mainly to legal acts that were adopted at a very early stage of the crisis.<sup>25</sup>

The latest proposal from the Commission included in the Financial Services measures, the proposal on key information documents for investment products (COM(2012) 352, has the drawback of increasing the administrative burden. The proposal reflects the need for increased transparency regarding investments, as the financial crisis has shown that retail investors lost money through investments that carried risks that were not transparent or understood by those investors. Investors have lost confidence in financial services and rebuilding confidence through transparency is vital. Greater transparency often goes together with increased administrative burdens, in this case by about EUR 171 million. As the Proposal was adopted by the Commission only on 3 July 2012, the final result of the legislative process in Council and Parliament is not included in the figures below.

The most relevant impact in terms of reduced administrative burden in this sector concerns the new provisions on large-exposure regimes under Directive 2009/111 (part of the CRD II package).

In the overview table for Financial Services, one figure for a change in the level of administrative-burden reduction is missing. This is because the measure refers to guidelines or similar provisions that, following the final adoption by the Council and Parliament, have been delegated to agencies (such as the Committee of European banking Supervisors). In such cases, no figures have been included in this final overview as it is not the responsibility of the Commission to prepare the guidelines.

<sup>&</sup>lt;sup>25</sup> An example concerns measure 4 of the CDRII package. The reduction in administrative burden will be offset by increased compliance costs stemming from additional requirements in relation to a more prudent approach in the area of interbank exposures (CRDII); to the enhanced disclosure for securitisations in banks' trading books (CRDIII) and to the new measures in the area of liquidity risk and counterparty credit risk management (CRDIV). The latter may have a lesser impact on the smallest EU banks with a simple balance structure.

Financial Services	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Revising capital and solvency requirements for credit institutions	+16.7	Adopted Directive 2006/48/EC of the European Parliament and of the Council of 14 June 2006	E: 20.07.2006
Revising mandatory and solvency capital requirements for insurance and reinsurance companies (Solvency II)	+0.9	Adopted.  Directive 2009/138/EC of the European Parliament and of the Council of 25  November 2009.	E: 6.01.2010 T: 31.10.2012
Reducing administrative burdens on 'Undertakings for Collective Investment in Transferable Securities' (UCITS)	- 45.0	Adopted. Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009	E: 7.12.2009 T: 1.07.2011
Simplifying rules on large exposures of credit institutions (CDR II package)	- 105.0	Adopted. Directive 2009/111/EC of the European Parliament and of the Council of 16 September 2009	E: 7.12.2009 T: 31.12.2010
Abolishing the obligation to report on initial capital, own funds and investment limitation for e-money service providers	-2.4	Adopted Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009	E: 31.10.2009 T: 30.04.2011
Reducing reporting obligations on cross-border payments	- 6.7	Adopted Regulation (EC) No 924/2009 of the European Parliament and of the Council of 16 September 2009	E: 30.10.2009 A: 1.11.2009
Simplifying the provision of pre-contractual information required from insurance companies	+171.0	Proposed COM(2012) 352 final	
Harmonising the format and frequency of reporting by credit institutions and investment firms	n/a	Adopted. Directive 2009/111/EC of the European Parliament and the Council of 16 09 2009.	E: 7.12.2009 T: 31.12.2010
Sectoral Total	29.5		

## 6. FISHERIES

Administrative burdens stemming from information obligations on Fisheries are the smallest among the 13 priority areas covered by the Action Programme for Reducing Administrative Burdens in the European Union in absolute terms (less than 0.1%). The Action Programme covers only one legal act regulating fisheries, Council Regulation (EEC) No 2847/93 (the 'Control Regulation'), which accounted for burdens estimated at EUR 73.9 million. On 14 November 2008, the Commission presented a proposal to replace Regulation (EEC) No 2847/93 that would halve the burden, in particular through the extensive use of electronic logbooks. This proposal was adopted in 2009 as Council Regulation (EC) 1244/2009.

It is worth noting that one of the measures included in the sectoral plan for fisheries had been proposed before the Programme was launched, using electronic reporting by way of electronic logbooks for vessels above a certain size, generating estimated savings of EUR 19 million. During implementation of the 2006-2008 Action Plan for Simplifying the Common Fisheries Policy (CFP)<sup>26</sup>, the Council had adopted in 2006 a reform introducing electronic reporting. This electronic reporting was included in Regulation (EC) No 1224/2009. Implementing measures were adopted in 2008 and the new system has been compulsory for sales data since 2009 and for catch data since 2010 for vessels larger than 24m; it is being gradually extended to vessels above 12m. However, as Regulation (EC) No 1224/2009 in the end extended the use of electronic logbooks to a smaller group of fishing vessels than originally proposed, the reduction of administrative burdens was less than originally envisaged. A reform of the system of fishing authorisations has also been introduced together with simpler rules for the European Maritime and Fisheries Fund.

<sup>&</sup>lt;sup>26</sup> COM(2005) 647.

Fisheries	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Using electronic logbooks for vessels 15 meters length overall and above	-19.0	Adopted. Council Regulation (EC) No 1224/2009 of 20 November 2009 and Commission Implementation Regulation (EU) No 404/2011 of 8 April 2011	1224/2009 E: 23.12.2009 A: 1.01.2010 404/2011 E: 7.5.2011
Extending the use of electronic logbooks to certain types of vessels	-6.5	Adopted. Council Regulation (EC) No 1224/2009 of 20 November 2009 (The ABR potential of the original proposal was 14 million EUR)	E: 23.12.2009 A: 1.01.2010
Introducing a standard method for fishing inspections across the EU	-0.4	Adopted. Council Regulation (EC) No 1224/2009 of 20 November 2009; and Commission Implementation Regulation (EU) No 404/2011 of 8 April 2011	1224/2009 E: 23.12.2009 A: 1.01.2010 404/2011 E: 7.5.2011
Sectoral Total	-25.9		

#### 7. FOOD SAFETY

The potential burden reduction estimated in this area takes into account EUR 103.8 million of additional administrative burdens that were estimated to be linked to the Commission proposal on food information to consumers. It must be noted, however, that the final adopted text, Regulation (EC) No 1169/2011 modernising the general food labelling and nutritional labelling regime, which responded to a strong request from stakeholders and industry, entails major achievements in terms of simplification and modernisation of the food-labelling rules: it recasts in a Regulation a considerable number of 'scattered' labelling provisions, reducing the information costs for food businesses and facilitating implementation by control authorities. It also introduces the principle of systematic use of transitory periods and the exhaustion of stocks in EU food-labelling legislation and of uniform implementation. In addition, it narrows the scope for national labelling rules. It provides the Commission with the legal basis to enable (via delegated acts) the provision of mandatory food information a) by other means than the label and b) by using logos or pictograms instead of words. This Regulation will enter into force in December 2014.

Among the measures adopted it is also worth noting that Regulation (EC) No 1069/2009 streamlining legislation on animal by-products (item 7) may lead to a burden reduction higher than the EUR 21.2 million initially estimated, according to a study carried out by an external contractor.<sup>27</sup> In addition, the elimination of veterinary border-inspection posts between the EU and Switzerland, thanks to the alignment of Swiss animal health and welfare standards with the European ones, will considerably reduce red tape for operators importing livestock and consignments of animal products from third countries via Switzerland (some 32 000 consignments per year).

The new proposal simplifying bovine identification procedures and repealing provisions on voluntary beef labelling will add savings worth EUR 0.4 million to the initial estimates in this field.

<sup>&</sup>lt;sup>27</sup> DG ENTR CEPS Brussels, 25 August 2009.

Food Safety	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Simplifying bovine identification procedures	- 0.4	Proposed.	
Repealing provisions on voluntary beef labelling	- 0.4	COM(2011) 525 of 30 August 2011	
Simplifying ovine identification procedures	n/a	Adopted Commission Regulation (EC) No 759/2009 of 19 August 2009	E: 10.09.2009
Reducing the number of veterinary checks on intra-community maritime trade	n/a	Adopted SANCO/10473/2009 — Guidance Document on procedures for checks on live animals and products of animal origin arriving at EU points of entry which have full veterinary clearance for the EU market	
Eliminating veterinary border-inspection posts between the EU and Switzerland	- 1.3	Adopted Decision no 1/2008 of the joint veterinary committee set up by the agreement between the EC and the Swiss Confederation on trade in agricultural products of 23 Dec. 2008	
Streamlining legislation on the production, marketing and use of animal by-products	- 21.2	Adopted Regulation (EC) No 1069/2009 of 21 October 2009 Implementing Regulation (EU) No 1142/2011 of 26 02 2011	E: 5.12.2009 A: 4.03.2011
Abolishing authorisation procedures and simplifying labelling requirements for feed materials	- 2.0	Adopted Regulation (EC) No 767/2009 of 13 July 2009	E: 21.09.2009 A: 1.09.2010
Setting a common and shorter authorisation procedure for food-improvement agents	- 0.1	Adopted Regulation (EC) No 1331/2008 Regulation (EC) No 1333/2008	1331 E: 20.01.2009 1333 E: 20.01.2009 A: 20.01.2010
Simplifying general food labelling and nutritional labelling	+103.8	Adopted Regulation (EC) No 1169/2011 of 22 November 2011	E: Food labelling 13 12 2014; nutritional labelling 13 12 2016
Sectoral Total	-78.8		

## 8. PHARMACEUTICAL LEGISLATION

The five information obligations in the priority area of Pharmaceutical Legislation that were scrutinised, reduced and simplified relate to the application needed for marketing authorisation, to notification of planned changes in the marketing authorisation, to submission of a periodic safety report, to requests for authorisation to commence a clinical trial and to the registering of detailed records of suspected adverse reactions.

Implementation of the new pharmaco-vigilance legislation not only enhances public health protection but will also mean a reduction of administrative burdens and greater simplification, once it is fully implemented. The intended streamlining of the processing of marketing authorisations for medicinal products for human use was covered by the simplifications introduced in the procedure for reporting 'Variations' (i.e. Commission Regulation (EC) No 1234/2008 of 24 of November 2008; Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009).

Once adopted by the legislator, the Commission proposal on the new Clinical Trials Directive would reduce administrative burdens by EUR 267.4 million per year — a figure up on the initial estimate of EUR 37.4 million, following a careful impact-assessment exercise. Furthermore, it would also reduce other compliance costs for persons conducting clinical trials ('sponsors') by over EUR 500 million per year. Once implemented, the measures proposed will speed up and simplify the authorisation and reporting procedures, while maintaining the highest standards of patient safety and robustness and reliability of data. The measures will also more closely match obligations to the risk-profile of the trial, improve transparency (including with regard to trials performed in third countries) and make it possible for the Commission to conduct controls in Member States and other countries to make sure that the rules are being properly supervised and enforced.

The total reduction potential of the measures included in this area has increased from EUR 154.6 million (initial estimate<sup>28</sup>) to EUR 368.5 million.

<sup>&</sup>lt;sup>28</sup> COM(2011) 544 Annex C, page 65

Pharmaceutical Legislation	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Simplifying the procedure for reporting 'Variations' (changes) to medicines already authorised for marketing	-40.0	Adopted Commission Regulation (EC) No 1234/2008 of 24 November 2008; Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009; and Commission Regulation (EU) No 712/2012 of 3 August 2012	1234/2008 E: 1.01.2009 A: 1.01.2010 712/2012 A: 2.11.2012; 3.08.2013
Simplifying pharmaco-vigilance reporting obligations	-61.0	Adopted Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010.	E: 1.01.2011 A: 21.07.2012
Simplifying the application to commence a clinical trial required to test new medicines	-267.4 (initially estimated 37.4)	Proposed. COM(2012) 369 of 17 July 2012 (2012/0192 (COD)) for a Regulation on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC)	
Simplifying Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin	-0.1	Adopted Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council	E: 6.07.2009
Streamlining the processing of the marketing authorisation for medicinal products for human use	n/a	Covered by the simplifications of the procedure for 'Variations' (item 1).	
Sectoral Total	-368.5		

## 9. PUBLIC PROCUREMENT

Public Procurement measures have led to an additional overall reduction of EUR 156.6 million compared to what was presented in the sectoral plan in 2009, thus amounting to a total reduction potential of EUR 216.6 million. This is due to the Commission proposal on public procurement COM(2011) 896, which cuts administrative burdens by requiring only the winning enterprise to submit tender documents. The negotiations in the Council and Parliament have not yet been finalised and thus the reduction potential indicated reflects only the Commission proposal.

The legislative proposal recognises the potential of e-procurement as a way to reduce the administrative burden of the public procurement directives. E-procurement benefits businesses by reducing the time and costs associated with public-procurement procedures. Realising this potential requires alignment on common architectures and processes for organising e-procurement procedures, and the use of inter-operable systems which are open to the widest possible range of potential tenderers. The Commission is therefore proposing that all MS should be capable of conducting their procurement electronically by 2016.

A complete specification for a 'Virtual Company Dossier' (VCD) for use by businesses in public-procurement procedures has been developed in the Pan-European Public Procurement Online (PEPPOL) project, partially funded by the EU. This VCD specification provides the means for a tenderer to assemble, and for a procurer to access, all the data required to verify the evidence, certificates and attestations which may be requested in calls for tenders. This specification is publicly available and is already in use by a number of contracting authorities and economic operators across the EU.

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Public Procurement	Change in the level of AB (million EUR)	State of play	Entry in force (E)  Application (A)  Transposition (T)
Only by the winning enterprise need submit the documents demonstrating suitability as a tenderer in a procurement procedure	-12.5	Adopted European Code of Best Practices Facilitating Access by SMEs to Public Procurement Contracts, SEC(2008) 2193	E: 25/6/2008
	-156.5	Proposed Revision of EU public-procurement Directives (COM(2011) 896 of 20 12 11. Negotiations in Council and Parliament are continuing in 2012.	
Creating a 'Virtual Company Dossier' for businesses in public-procurement procedures	- 47.6	A full specification developed in a pilot project (PEPPOL VCD) has been available since May 2012	
Creating an online information database on business certificates for public-procurement procedures	n/a	E-CERTIS on-line database launched in Nov 2010 — about 70'000 document downloads since launch	A: 20/10/2010
Sectoral Total	-216.6		

## 10. STATISTICS

Legislation in the area of statistics accounts only for a small part of the total administrative burden in the EU. Nevertheless, statistical surveys give rise to irritation and the perceived burden of statistics is often higher than the real burden. This part of EU legislation is output orientated: it defines what a Member State has to deliver in terms of statistical information but not how this information has to be collected; each Member State decides how it will produce the necessary data. This means that effective reduction of administrative burdens relies to a large extent on the Member State.

Under the Action Programme, 11 measures have been adopted with estimated savings for business equivalent to EUR 329.6 million; it has been proposed that two other measures be included in Member States' programmes.

As further major burden reduction could have an impact of the quality and relevance of the data, a strategy<sup>29</sup> to build a modern and integrated statistical system was developed by the Commission to improve the efficiency of the production process of statistics. A new legal framework for the production of European statistics<sup>30</sup> paved the way for re-engineering the whole architecture of the European Statistical System (ESS).

In the area of business and trade statistics, this strategy is supported by the Programme for the Modernisation of European Enterprise and Trade Statistics (MEETS).<sup>31</sup> Projects within MEETS include improving legal and technical aspects of data collection for Intrastat (including studying the possibility of introducing a single-flow reporting system), more efficient use of administrative data in business statistics and Intrastat and the linking of micro data from different surveys used in business and external-trade statistics.

The most relevant measures for business are the early amendment introduced to Regulation EC) 638/2004 which enabled Member States to remove a large number of companies from Intrastat reporting obligations by decreasing the minimum coverage rate of intra-EU imports from 97% to 95%, in terms of value, and a measure adopted in 2012 to reduce reporting requirements on road transport (Regulation (EU) No 70/2012).

On the whole, results in this area must be considered positive.

<sup>9</sup> COM(2009) 404 on the production method of EU statistics: a vision for the next decade.

Regulation (EC) No 223/2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities, in force from 1 April 2009.

Decision No 1297/2008/EC of the European Parliament and of the Council of 16 December 2008 on a Programme for the Modernisation of European Enterprise and Trade Statistics.

Statistics	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Reducing the number of respondents when compiling statistics on intra-EU trade	- 1 34.3	Adopted. Regulation (EC) 638/2004 of 31 March 2004	E: 27.04.2004 A: 1.01.2005
Reducing the administrative burden on businesses by supporting MS in making better use of administrative data and introducing enhanced and more efficient e-Gov solutions to collect data	n/a	Completed. Decision No 1297/2008/EC of the EP and of the Council of 16 December 2008 on the MEETS Programme, implemented by annual work programme 2009-2012	
Updating the statistics on fruit trees in line with today's needs	n/a	Adopted. Regulation (EU) No 1337/2011 of 13 December 2011 concerning European statistics on permanent crops and repealing Council Regulation (EEC) No 357/79 and Directive 2001/109/EC	
Reducing reporting obligations on pig livestock and meat	- 3.7	Adopted. Regulation (EC) No 1165/2008 of 19 November 2008	E: 21.12.2008 A:1.01.2009
Reducing reporting obligations on bovine livestock and meat	- 1.2	Adopted. Regulation (EC) No 1165/2008 of 19 November 2008	E: 21.12.2008 A:1.01.2009
Reducing reporting requirements on industrial production in the EU	- 101.6	Adopted Annual Prodcom lists implementing Council Regulation 3924/91 (e.g. Commission Regulation (EC) No 36/2009 of 11 July 2008)	E: latest 11.02.2009, A: 1.01.2008, 1.01.2007, 1.01.2006.1.01.2005
Reducing reporting requirements for Structural Business Statistics	- 19.0	Adopted. Regulation (EC) 295/2008 of 11 March 2008	E/A: 29.04.2008
Reducing the administrative burden for businesses stemming from Structural Business Statistics surveys	Discussions on going n/a	Proposed to Member States, to be implemented as part of the Framework Regulation Integrating Business Statistics.	
Reducing reporting requirements for statistics on Information and Communication Technologies	- 3.7	Adopted. Commission Regulation (EC) No 847/2007 of 18 July 2007 Commission Regulation (EU) No 937/2011 of 21 September 2011 concerning Community Statistics on the Information Society	E/A: 8.08.2007
Reducing reporting requirements for producing Short-Term Statistics	-64.8	Adopted. Regulation 1158/2005 of 6 July 2005 Initial estimated BR 64.8	E/A: 11.08.2005
Reducing reporting requirements for statistics on tourism	-1.3	Adopted. Regulation (EU) No 692/2011 of the EP and Council 6.07.11 concerning European statistics on tourism and repealing Council Directive 95/57/EC	E/A: 11.08.2011
Reducing reporting requirements on road transport	n/a	Adopted. Regulation (EU) No 70/2012 of 18 January 2012 on statistical returns in respect of the carriage of goods by road	E/A: 08.02.2012
Simplifying the legislation relating to statistics on sea transport	n/a	Adopted. Commission Decision of 14 April 2010 amending Directive 2009/42/EC of the European Parliament and Council	E/A: 16.4.2010
Sectoral Total	-329.6		

#### 11. TAXATION AND CUSTOMS

Taxation and Customs legislation is considered the most important priority area in terms of administrative costs and burdens imposed on businesses. Under the Action Programme, six measures have been adopted and one is pending.

The Invoicing Directive adopted in 2010 will take effect from 1 January 2013. The Directive creates equal treatment between paper and e-invoices and no longer allows Member States to prescribe a certain technology for e-invoices. It is estimated that if all businesses adopted e-invoicing savings would amount to EUR 18 billion in the medium term, which represents a 26% reduction in VAT administrative burdens. DG TAXUD has issued Explanatory Notes on invoicing (published on the Commission's website on 5 October 2011) which should help inform businesses of the changes and encourage Member States to implement provisions in a consistent manner.

The Refund Directive provides for electronic submission in the Member State where the business is established of VAT refund claims from other Member States. Its administrative burden reduction potential is estimated at EUR 447 million (1 % burden reduction).

The VAT Package established a general rule concerning the place of supply for B2B services. From 2015, the place of supply for B2C supplies of telecoms, broadcasting and e-services will be where the customer belongs, thus ending VAT-rate distortions. With the mini-One Stop Shop, VAT on B2C telecoms, broadcasting and e-services due in Member States where the supplier is not established can be declared and paid in the Member State of the supplier. Its burden-reduction potential is estimated at EUR 463 million (1%).

The Modernised Customs Code and the e-Customs decision aim at achieving a major change in the way economic operators accomplish customs formalities and Customs perform controls. It implies reducing significantly administrative burden in customs activities; developing a fully electronic customs environment based on streamlined and more unified rules; and the setting up of interoperable electronic systems. However, the application of the Modernised Customs Code, initially planned in June 2013, will be postponed through a recast of the regulation aiming to align it to the Treaty on the functioning of the EU, to introduce limited corrections, and to "phase in" the extensive IT developments involved in the application of the new legislation. The proposed new date of application is 1January 2015, but it will depend on the outcome of the on-going legislative procedure.

Taxation and Customs	Change in the level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Suppressing additional requirements on invoices and enabling wider use of electronic invoicing	- 18803.8	Adopted Council Directive 2010/45/EU of 13 July 2010	E: 11.08.2010 T: 1.01.2013
Suppressing, in the VAT refund procedure, the obligation to fill out paper forms in the language of the Member State of refund	- 447.0	Adopted Council Directive 2008/9/EC of 12 February 2008	E: 20.02.2008 T: 1.01.2010
Simplifying the rules concerning the place of supply of services (mini-One Stop Shop)	- 463.0	Adopted Council Directive 2008/8/EC of 12 February 2008	E: 20.02.2008
Setting up a One Stop Shop and increasing thresholds of special schemes for SMEs and distance sales	- 4397.4	Proposed. CNS/2004/0261 — Proposal for a Council Directive COM(2004) 728 of 29 October 2004. Awaiting Council Decision	
Adapting the frequency of the recapitulative statements on cross-border transactions and switching to an electronic procedure	+203.9	Adopted Council Directive 2008/117/EC of 16 December 2008	E: 21.02.2009 T: 1.01.2010
Modernising customs procedure and especially the switch to a fully electronic customs procedure (legislative proposal)	- 2427.0	Adopted Regulation (EC) No 450/2008 of 23 April 2008 is however under recast (to revise and align with the Treaty of Lisbon). Application to be postponed to 1 January 2015 at the latest (to be confirmed). ; Decision No 70/2008/EC 1 of 15 January 2008	450/2008:E: 24.06.2008 A: postponed 70/2008: E 16.02.2008
Simplifying Regular Shipping Services	n/a	Adopted Commission Regulation (EU) No 177/2010 of 2 March 2010	E 10.03.2010 Points 2 and 3 of Art. 1A 01.01.2012
Sectoral Total	-26334.3		

#### 12. TRANSPORT

The process of simplification and modernisation which had started even before the Action Programme in 2007 has been carried further in the Strategy for a Single European Transport Area initiated in 2010. Over the last few years, the administrative burden due to existing EU transport legislation has been reduced by more than half a billion euros per year.

The bulk of the reduction was achieved by updating and simplifying the rules on tachographs for road transport, for instance reducing the time spent on registering and transmitting information through the introduction of digital tachographs and by simplifying the use of digital tachographs. These measures will benefit SMEs in particular because a large majority of road-transport companies are SMEs. A further big package of tachograph-simplification measures suggested by the Commission in 2011 is still under discussion in the European Parliament and Council. It would exempt craft businesses from tachograph requirements for journeys shorter than 100 km, facilitate the remote downloading of data from tachographs and integrate the current digital tachographs into onboard computers. This could reduce the administrative burden by another half billion euros. However, the Council in its general approach of June 2012 and the European Parliament in its first reading in July 2012 did not include the Commission's proposal to merge the driver card and driver licence, a measure which could have saved another EUR 100 million.

Other considerable burden reductions were achieved in the area of transport-tariff notifications and the formalities for short sea shipping. The latter is fully in line with the Commission's objective of making non-road transport (in particular rail freight, inland water transport and short sea shipping) in the EU more attractive and so increase the environmental sustainability of the transport sector.

All legislative initiatives adopted by the European Parliament and the Council in the framework of the transport sectoral programme have already entered into force and are applicable. The Commission encourages the co-legislators to agree on the further tachograph package proposed in 2011 as soon as possible, so that a further 400 to 500 million euros of unnecessary administrative burden can be cut.

Transport	Change in level of AB (million EUR)	State of play	Entry in force (E) Application (A) Transposition (T)
Reducing time spent on registering and transmitting information on road transport through the introduction of digital tachographs	- 286.6	Adopted Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006	E 11.04.2007 except: 10(5), 26(3), (4) & 27 E 01.05. 2006
Simplifying the use of digital tachographs and improving the 'form of attestation" covering the driver's activities'	- 234.5	Adopted Commission Regulation 1266/2009 of 16 Dec. 2009 and Commission Decision of 14 Dec. 2009	E 11.01.11; A 1.10.11 (3.1, 3.8, 3.9, 3.11, 3.20, 8,.2, 9.2, 12.3, 12.4 and 13 of the Annex A 1.10. 12
Exempting small craft businesses from tachograph requirement for short journeys	-415.0 (initial	Included in the Commission proposal for amending Regulation 3821/85 of 19 July 2011 (estimated reduction -52.8)	
Facilitating remote downloading of data from the tachograph and driver card	estimated reduction -515)	This measure is included in the Commission proposal for amending Regulation 3821/85 of 19 July 2011(estimated reduction -34.5)	
Integrating the current digital tachographs into onboard computers	See point 3	Partly included in the Commission proposal for amending Regulation 3821/85 of 19 July 2011under 'ITS standard interface'	
Making broader national use of all exception categories defined in the EU tachograph regulation	See point 3	Partly included in the Commission proposal for amending Regulation 3821/85 of 19 July 2011	
Facilitating cross-acceptance of rolling-stock	- 0.4	Adopted. Directive 2008/57/EC of the EP and Council of 17 June 2008	E 18.07.2008 A 19.07.2008
Simplifying obligations for road haulage and road passenger transport	- 34.9	Adopted Regulation 1071/2009 of 21/10/2009 and Regulation 1072/2009 of 21/10/2009	1071/2009: E: 23.11.2010 A: 24.11.2010 1072/2009 E: 12.12.2009 A: 4. 12. 2011 (exc. Art 8.9 A 14.05.2010)
Simplifying EU legislation on the inland transport of dangerous goods	- 2.2	Adopted Directive 2008/68/EC of the Eur. Parliament and of the Council of 24 September 2008	E: 20.10.2008
Abolishing the notification of transport tariffs and alleviating the obligation to keep documentary evidence on board	- 114.7	Adopted Council Regulation (EC) No 569/2008 of 12 June 2008	E: 20.06.2008 A: 11.07.2008
Reducing formalities in Short Sea Shipping	- 75.0	Adopted Directive 2010/65/EU of the European parliament and the Council of 20 October 2010	:E 29.10.2010 A: 19.05.2012
Sectoral Total	- 1163.3		

## 13. WORKING ENVIRONMENT / EMPLOYMENT RELATIONS

The objective of the Action Programme in the working environment/employment relations sector was to cut unnecessary burdens on businesses, keeping in mind that the right to working conditions which respect workers' health, safety and dignity and the right to information and consultation within the undertaking are fundamental rights of every worker in the EU as recognised by the 'Charter of Fundamental Rights of the European Union'. In other words, the aim was to examine what burden could be suppressed without compromising the achievements already attained in terms of levels of protection and the reduction of occupational accidents and illnesses.

The Sectoral Reduction Plan for the working environment/employment relations sector has encountered a number of difficulties in the implementation process. Several stakeholders in the various interest groups of the Advisory Committee on Safety and Health at Work (governments, employers and workers) have been very critical of the Action Programme as it focuses mainly on costs and quantification, which has proven to be a difficult concept to apply in the area of occupational health and safety. The risk of focusing on the costs and the quantitative aspects of EU measures, neglecting the benefits and qualitative aspects, has been pointed out. Another issue is the fact that in the area of health and safety it is often difficult to obtain data on the situation in SMEs and even more so in the case of micro enterprises.

To meet the targets of the Action Programme, a number of initiatives have been taken that mainly took the form of guidelines or tools that sought to facilitate compliance by enterprises with obligations set by legislation (for details, see the table below).

Working Environment/Employment Relations	Change in the level of AB (million EUR)	State of play	Entry in force (E)Application (A) Transposition (T)
Improving the guidance for businesses on the health and safety of workers	- 92.5 (reduction of costs resulting from the Common Principles still needs to be assessed)	Adopted  The European Agency for Safety and Health at Work, 'Guidance on Risk Assessment — tool & check list' (2006, 2007); 'SLIC Common Principles for Labour Inspection in relation to Health and Safety in the Workplace' (revised 2006).	
Easing the drafting of risk assessments on health and safety in businesses	n/a	Adopted The European Agency for Safety and Health at Work launched OiRA (Online interactive Risk Assessment Tool) on 13 September 2011	
Making labour inspection visits more efficient	n/a (still to be assessed)	Achieved through other means The measure has been achieved through the methods for sharing knowledge and good practice of the 'Senior Labour Inspectors' Committee' (SLIC), as well as their Common Principles for Labour Inspection. These principles set a benchmark for all EU labour inspection services as they provide a framework for the organisation of a modern labour inspection system The reduction potential of this has not yet been estimated.	
Improving the guidance for construction-site enterprises	- 140.0	Adopted Guidance document was published in English in March 2011 (other languages to follow).	
Improving the efficiency of regulations concerning the European Works Councils	-0.02	Adopted Directive 2009/38/EC of the European Parliament and of the Council of 6 May 2009 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 (recast)	E 16.05.2009 A 6.06.2009 T 05.06.2011
Sectoral Total	- 232.5		