



EUROPEAN COMMISSION

High Level Group of Independent Stakeholders on Administrative Burdens

OPINION OF THE HIGH LEVEL GROUP

Subject: Stakeholders' suggestions ('offline-consultation')

I. Background

- (1) The High Level Group of Independent Stakeholders on Administrative Burdens (HLG) was set up to *inter alia* advise the Commission on suggestions for administrative burdens reduction measures. In addition to the suggestions by consultants, via the online consultation or on the occasion of local workshops with businesses in Member States, the HLG members and the Commission receive occasional reports or letters by external stakeholders suggesting reduction ideas. These ideas have been labelled "offline suggestions".
- (2) Mr. Linschoten was appointed coordinating reporting member for these offline suggestions. The HLG works on these suggestions in the following way: at first the secretariat assesses the incoming proposals with the help of those Directorates-General of the Commission that are competent in the subject matter. At the same time suggestions are filtered out which do not concern European legislation at all. Secondly, the group's reporting members look at suggestions in their respective priority area for which first reactions from Commission services are available. The result of this process is an opinion of the group addressed to the Commission.
- (3) The HLG calls upon the college of Commissioners and Commission services to take all necessary steps to ensure that legislative proposals are introduced in time. The HLG wishes to underline that achieving the aim of a reduction of administrative burden by 25 % by 2012 will only be feasible with as many concrete reduction measures as possible.

II. General comments

- (4) So far the HLG has received several hundred ideas from stakeholders. The HLG has adopted three opinions on the offline consultation in its meetings of 18 September 2008, 20 January and 16 April 2009¹.

¹ Cf. http://ec.europa.eu/enterprise/admin-burdens-reduction/highlevelgroup_en.htm

- (5) For the current opinion the HLG decided to focus mainly on suggestions received from national governments, in particular from Denmark, the Netherlands and the UK. In addition, a few suggestions received in the context of the competition for the Best Idea for Red Tape Reduction Award² have been taken up for this opinion.

III. Suggestions by Priority Area

- (6) *Priority Area Company Law.* Suggestions 1 and 2 concern the Second Company Law Directive.³ Stakeholders suggest modernising the directive and in particular providing an alternative system to the current mandatory minimum capital system, in order to require less capital for the start-up of a business. This is one of the main conclusions of the KPMG research done on behalf of the Commission. The Commission is of the view that the current capital maintenance regime does not seem to cause significant operational problems for companies. *The HLG urges the Commission to initiate a debate with the Member States and stakeholders based on the abovementioned report and to come forth with a proposal addressing this suggestion.*
- (7) *Priority Area Company Law.* Stakeholders suggest repealing the requirements for the internal operations of one-member companies contained in the Twelfth Company Law Directive⁴ (suggestion 3), so that the directive would only include the basic deregulatory requirement that companies setting up subsidiaries in another Member State do not have to find a second, local nominee member and may have only one member or shareholder. In light of the experience with simplification proposals currently negotiated in the European Council and the European Parliament, the Commission will look into this issue at a later stage. *The HLG supports this suggestion and calls for a revision of the Twelfth Company Law Directive. In this context, the Group also recalls its opinion on company law of 10 July 2008⁵, and in particular paragraphs 53-56 on the Twelfth Directive. With respect to simplification proposals already tabled the HLG is of the view that the European Parliament and the Council should adopt these proposals as soon as possible since they take account of stakeholders' comments and contribute to reducing administrative burden for companies. The current crisis does not allow further delays.*
- (8) *Priority Area Pharmaceutical Legislation.* Suggestion 4 points at excessive burdens due to complex definitions of 'medicinal product' and 'medical device' which do not

² Cf. <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/754&format=HTML&aged=0&language=EN&guiLanguage=en>; http://ec.europa.eu/enterprise/admin-burdens-reduction/competition_en.htm

³ Second Council Directive 77/91/EEC of 13 December 1976 on coordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, in respect of the formation of public limited liability companies and the maintenance and alteration of their capital, with a view to making such safeguards equivalent

⁴ Twelfth Council Company Law Directive 89/667/EEC of 21 December 1989 on single-member private limited-liability companies

⁵ Cf. http://ec.europa.eu/enterprise/admin-burdens-reduction/docs/080710_hlg_op_comp_law_final.pdf

allow for clear classifications of products. In these cases, it can take a lot of time and effort to reach a decision which legislation should be applicable to a particular product. The underlying and preliminary issues concern the technological and scientific developments, which lead to a growing convergence and coherence between medical devices and medicinal products. Stakeholders therefore suggest improving the coherence between the respective definitions. Furthermore, in their view the coherence between the requirements for quality, safety and efficacy / functionality of medicinal products and medical devices should also be improved and be based on an extensive risk analysis of the product. This would lead to a less labour-intensive market access for new products while maintaining the same level of quality and safety. The Commission will address the delineation between medical devices and medicinal products in the context of its proposal on medical devices which is currently under preparation. It points to an existing procedure for cases of doubt (so-called 'Helsinki procedure' of inter-Member-State consultation) and the existence of a specialised expert group⁶. *The HLG underlines its recent advice on this issue in the opinion on the priority area Pharmaceutical Legislation of 5 March 2009 to assess the relevant legislation in an integrated way in order to improve the coherence between both legislations. In particular, improvements should be made on the coherence of the interpretation of the definitions of medical devices, medicinal products and consumer goods. Furthermore, the HLG urges the Commission to come forth with a coherent set of requirements for both the medical products and devices. These requirements should be risk-based.*

- (9) *Priority Area Working Environment.* In suggestion 5 stakeholders call for a better alignment of EU legislation on the production and use of safety signs⁷ with the rules of international standards (ISO) for illuminated signs and ask for further clarifications. The Commission is aware of the issue of harmonising the directive with international standards and intends to launch works to examine this issue. *The HLG supports the suggestion and calls on the Commission to examine the issue and harmonise requirements wherever possible with a view to reducing unnecessary administrative burdens.*
- (10) *Priority Area Agriculture.* Suggestions 6 – 13 concern certain aspects of the direct payment system regulated in Commission Regulation (EC) No 796/2004 on the implementation of cross-compliance, modulation and the integrated administration and control system. Stakeholders suggest allowing Member States to recalculate the value of the payment entitlements in case the farmer owns various fractions of an entitlement of the same origin. They suggest exempting farmers who use less than one hectare from the obligation to submit a single application for payments and abolishing the obligation to submit certain supporting documents as specified in Art. 13 of Regulation (EC) No 796/2004 with the single application (since they are only necessary in case of physical checks, so that it suffices that the farmer keeps the documents available for the control officials). Moreover, they argue for allowing Member States to apply the measurement tolerance as referred to in Art. 30 (1) of Regulation (EC) No 796/2004 also with respect to administrative checks based on the

⁶ Borderline and Classification Medical Devices Expert Group

⁷ Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work

Geographical Information System as referred to in Art. 6 (1). They also suggest allowing advance payments in case of parcel⁸ overlapping once the margins of the total amount of possible aid have been established by the national authorities, and integrating the above mentioned regulation and Regulation (EC) No 1975/2006 into one regulation, since both regulations deal with more or less the same matter while at the same time deviating in details such as definitions. Furthermore, stakeholders request more flexibility in cases of missing or incomplete accompanying documents, in particular since many applications are lodged in the final days of the application period and cannot be checked on their completeness within the application period any more. In addition, they suggest changing the reference to “three years” into “three calendar years” within the definition of a “repeated non-compliance” in Art. 41 of Regulation (EC) No 796/2004, in order to allow for an easier application of the rule. Estimates for the administrative burden reduction range from €10,000 (fractions of entitlements) to €6.7 m. (exemption for less than one hectare) for the Netherlands. Stakeholders moreover suggest introducing a triviality limit regarding deviation between the agricultural parcels as declared in the single application and the reference parcels as contained in the identification system for agricultural parcels (suggestion 14). The Commission points out that during the Agricultural Council in April, thirteen national delegations submitted a list with 39 proposals for simplification of the Common Agricultural Policy (CAP) in the context of the Council discussions on the Commission’s March 2009 Communication on a simplified CAP for Europe⁹ including the above. The Commission has committed itself to examine these suggestions thoroughly and to report back to the Council in November. *A broad support exists among stakeholders for the simplification of the CAP. On a first screening, the ideas seem to merit an intensified effort for their implementation. The HLG asks the Commission to speed up its evaluation and take the necessary steps for a quick implementation where appropriate.*

- (11) *Priority Area Agriculture.* In the view of some stakeholders the cost of the controls related to dried fodder (Art. 27 of Regulation (EC) No 382/2005) are no longer proportionate to the total amount of aid granted. Thus, they suggest allowing an annual check instead of regular additional checks, which could reduce administrative burdens by approximately €44,000 for the Netherlands (suggestion 15). *The HLG supports this suggestion and encourages the Commission to take the necessary action.*
- (12) *Priority Area Food Safety.* Stakeholders suggest allowing transport documentation – currently to be carried in paper format in the means of transport during transport – to be available in an electronic reader or in a central database (suggestion 16). *The HLG points out that electronic means are one of the most appropriate ways to reduce administrative burdens for businesses if implemented correctly. The HLG therefore supports this suggestion and calls upon the Commission to take the necessary steps. In the view of the HLG the EU and the Member States should review cases which so far foresee only paper format with a view to allowing electronic means at least as an alternative to paper format in appropriate cases.*

⁸ An agricultural parcel is an area of land on which a single crop group is cultivated.

⁹ COM(2009) 128 final : A simplified CAP for Europe – a success for all.

- (13) *Priority Area Food Safety.* Suggestion 17 concerns a trade document used in the trade of animal by-products. Stakeholders argue for reducing the size of the trade document to one page only, and in particular for removing the ‘declaration of the transporter’ from this document. In addition, they emphasize that it should also be possible to use an electronic version of this document. According to the stakeholders this could reduce administrative burdens by €1.25 m. to €6 m. in the Netherlands alone. *The HLG supports this suggestion and encourages the Commission to make the necessary changes.*
- (14) *Priority Area Food Safety.* Suggestions 18-20 concern Directive 2000/13/EC on the approximation of laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. In these cases, stakeholders call for less detailed requirements, the introduction of a common commencement date once a year and suitable transition periods. Furthermore, they suggest digitalising the information on ingredients and limiting the information on the product to what is necessary for the majority of consumers. Producers who sell pre-packed products for direct sale should be able to provide additional information through other channels such as websites, consumer contact points or information in the shops (e.g. via computer screens). According to the stakeholders this could reduce administrative burdens by €74 m. to €111 m. in the Netherlands alone. The Commission recalls that it has adopted a proposal for a Regulation on the provision of food information to consumers that consolidates and updates two areas of labelling legislation (Directive 2000/13/EC for general foods and Directive 90/496/EEC for nutrition labelling), which contains provisions on the use of alternative means of information in the future and under certain conditions. According to the Commission the current labelling requirements have been considered by consumers and Member States as a valuable acquis to be maintained. *Many stakeholders point out the excessive burdens caused by the obligations originating from this directive. The HLG therefore calls upon the Commission to assess on a short notice the possible simplifications and to enable the digitalisation of information.*
- (15) *Priority Area Fisheries.* Stakeholders suggest developing one effort management regime which contains all the effort regimes¹⁰ for the different species currently spread over different management and recovery plans (suggestion 21). The Commission is aware that different effort regimes may create administrative burdens and thinks about moving towards a regional, multi-species approach in the long term. However, it also warns that this would create enormous scientific challenges and governance problems. *The HLG acknowledges the possible scientific challenges and encourages the Commission to assess the potential of regional, multi-species approaches for simplification and quick and effective reductions of administrative burdens for fishermen.*
- (16) *Priority Area Public Procurement.* Stakeholders suggest removing the obligation for contracting authorities to publish a simplified contract notice before they can issue an invitation to tender inviting all interested economic operators to submit an indicative tender within a time limit not less than 15 days, in order to encourage the use of the

¹⁰ Fishing effort regime refers to the fisheries system based on the management of the fishing effort. Fishing effort means the product of the capacity and the activity of a fishing vessel; for a group of vessels it is the sum of the fishing effort of all vessels in the group.

dynamic purchasing system (suggestion 22). In addition, they suggest introducing an option into the restricted procedure to allow contracting authorities to let the procedure be conducted in successive phases, in order to gradually reduce the number of candidates to a minimum of three (suggestion 23). According to stakeholders the administrative burdens could be reduced by €3.7 m. to €6 m. by the first idea, and between €1 m. to €1.7 m. by the second idea for the Netherlands. The Commission welcomes the contributions which will be taken into account in the scheduled evaluation of the EU public procurement Directives. However, any changes to the procedures will have to ensure that the principles of transparency and non-discrimination of bidders are fully respected. *The HLG supports both suggestions. In the dynamic purchasing system contracting authorities should have the possibility to deviate from the obligation to publish a simplified contract notice before issuing an invitation to tender. In the restricted procedure, successive phases could be introduced to reduce the burdens for the candidate companies. The HLG calls upon the Commission to initiate the necessary changes.*

- (17) *Priority Area Financial Services.* Stakeholder suggestions 24 – 26 point at the reduction potential related to the record keeping obligation under Directive 2004/39/EC on markets in financial instruments ('MiFID'; cf. Art. 25(2) MiFID, Art. 51(1) Directive 2006/73/EC). Stakeholders notably suggest reducing the time, that these records have to be kept, from five to three years, and deleting the options for Member States to require investment firms to keeping their records for even more than five years and to keep records for five years after termination of their authorisation. They furthermore ask for clarification of what data needs to be kept. The Commission has expressed doubts with regard to the reduction potential of the shortening of the time period and points out that it is upon Member States to make use or not of the options. *In the HLG's view the reduction of the time that a record has to be kept will allow for a burden reduction. Therefore, the HLG urges the Commission to encourage Member States to make use of the possibility to shorten the time period of record keeping. In addition, clarification should be given to businesses on what data should be kept.*
- (18) *Priority Area Financial Services.* Stakeholder suggestions 27 and 28 concern the obligation of re-insurance undertakings to inform authorities about their shareholders / members who have a qualifying holding (Art. 12 and 19 Directive 2005/68/EC). Stakeholders suggest excluding captive undertakings from these obligations because persons who are insured and shareholders / members holding the qualified holding are often the same persons. The Commission points out that it considers it more appropriate to look at the issues as a whole in the context of the Solvency II project, rather than considering an amendment to the two articles mentioned alone. *The HLG advises the Commission to address this issue within the context of Solvency II, and urges the Commission to alleviate the administrative burden caused by the abovementioned articles by introducing at least a lighter testing regime for shareholders and holders of a qualifying holding in captive reinsurance companies.*
- (19) *Priority Area Financial Services.* Stakeholder suggestion 29 refers to special information obligations imposed on credit institutions when these deal with politically exposed persons, such as the obligation to establish the source of the funds involved and the requirement to conduct enhanced ongoing monitoring of the business relationship (Art. 13(4) Directive 2005/60/EC). Stakeholders point out that not all politically exposed persons pose the same risk and therefore request a more risk-based

approach. The Commission refers to the international origin of these information obligations and states that the Directive already allows a risk-based approach. It furthermore stresses that efforts are already made to promote the implementation of this risk-based approach among national authorities and enterprises. *The HLG appreciates the efforts made by the Commission to promote the use of a risk-based approach. Nevertheless, the HLG advises the Commission to look for additional methods to promote this use even further such as the exchange of best practices. Besides, the HLG urges the Commission to assess the possibilities to limit the scope of this obligation. The HLG urges Member States to promote the possibilities of a risk-based approach on the national level, so that this irritant can be addressed accordingly.*

- (20) *Priority Area Financial Services.* Stakeholder suggestion 30 asks for a simplification of the rules on the transfer of the portfolio of contracts of credit institutions and investment firms to an accepting office established within the Community. Stakeholders suggest that the currently required permission from every retail client is replaced by a general authorization by the Member State in which the enterprise has its head office. The Commission points out that these rules are to ensure that the office, where the assets are transferred to, meets the prudential requirements. *The HLG supports this suggestion and advises the Commission to assess the possibilities of this simplification.*
- (21) *Priority Area Financial Services.* Stakeholder suggestion 31 points at the burden reduction potential of harmonising financial accounting standards and insurance undertaking solvency rules, so as to avoid that insurance undertakings have to perform burdensome double reporting obligations. The Commission fully supports the approach to reduce double burdens, but underlines that there are limits due to a difference in information needs. Both sets of rules are developed on different regulatory levels and follow different objectives. On the international level efforts are made to make parallel reporting possible. *The HLG advises the Commission to encourage where possible the reduction of the double burden by interlinking the international and the European information obligations.*
- (22) *Priority Area Financial Services.* Stakeholders point out that the pre-contractual information requirements for the distance selling of financial services differ from specific information requirements for services for some individual financial services within the meaning of the Financial Services Distance Selling Directive¹¹ (FSDSD; suggestion 32). For instance, provisions in the Insurance Mediation Directive¹² require only the name and the address of the insurance broker, while the respective provision in the FSDSD requires information on the main business activity or the address of every branch which is relevant for the business relations between consumers and providers. According to the stakeholders this occasions considerable extra work for financial service providers without providing any additional information for consumers in return. One possible solution for stakeholders would be to focus on information specific to distance selling and abolish the pre-contractual information requirements for specific providers and services in the FSDSD. In the Commission's view the overlapping pre-contractual information requirements have to be seen in a

¹¹ Directive 2002/65/EC concerning the distance marketing of consumer financial services

¹² Directive 2002/92/EC on insurance mediation, cf. Art. 12; in addition, cf. Art. 5 of Directive 2008/48/EC on credit agreements for consumers and Art. 19 (3) and (7) MiFID.

broader context. First steps to remedy the situation have already been taken, a study and legislative proposals might follow. *The HLG supports the stakeholders' request for a standardisation of (pre-contractual) information requirements and advise the Commission to prepare the necessary legislative proposals.*

- (23) *Accountability for receiving government grants.* Stakeholders call for proportional accountability requirements for small government grants of up to € 50,000, i.e. to disperse these grants on a basis of a lump sum instead of real costs, but with an explicit reference to non-interference with the internal market (state aid; suggestion 33). Afterwards, performance-based sample checks on the basis of risk analysis are carried out for control purposes. In the stakeholders' view the current accountability requirements are not proportionate, in particular for smaller beneficiaries. According to stakeholders this could reduce administrative burdens by €45 m. to €60 m. for the Netherlands alone. *The HLG supports this suggestion, and advises the Commission to take the necessary steps.*
- (24) *Data Protection.* Suggestions 34 and 35 concern Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Stakeholders suggest a harmonisation of data that need to be reported by companies with offices in several Member States (Art. 19), and argue for mutual recognition of reports in another Member State, if a company carries out the same handling of data in several Member States. In addition, they call for a limitation of cases in which persons concerned by personal data being processed has to be informed (Art. 12). According to stakeholders the administrative burdens could be reduced by € 150,000 to €4 m. by the first idea, and between € 120,000 to € 590,000 by the second idea for the Netherlands. *The HLG supports the first idea. The Group asks the Commission to study the potential for the suggested limitation of cases (second idea), while fully acknowledging the rights of access to information about processed personal data.*
- (25) *Pressure equipment.* A stakeholder calls for a simplification of Directive 97/23/EC concerning pressure equipment, in particular with respect to district heating (suggestion 36). Following contacts of the Commission with the stakeholder, it turned out that the main issue was related to pipelines for district heating which are in fact excluded from the scope of the directive and subject to national regulation. According to the stakeholder the authorities seem to review their position on this matter which would solve the issue. For pressure equipment used for large scale generation of hot water or steam (installed on site of the energy / heat supplier) which falls within the scope of the directive, the directive provides for balanced conformity assessment procedures proportionate to the safety risks according to the Commission. *The HLG welcomes that the main issue is about to be solved on national level. The Group takes the opportunity to point at the shared responsibility of EU and national levels for reducing burdens for companies.*
- (26) *Mandatory Conformity marking for products sold in the European Economic Area, CE-Marking*¹³. Suggestions 37 – 39 refer to Regulations (EC) No 764/2008, (EC) No

¹³ The CE marking (also known as CE mark) certifies that a product has met EU consumer safety, health or environmental requirements. The simplest way is a completely internal risk assessment, called module A. The system is based on eight modules from A to H. Between module A and H is an increasing requirement on the documentation test and certification procedures. The procedures have to be approved by a notified body.

765/2008 and Decision No 768/2008/EC on a common framework for the marketing of products. These legislative acts are known as the “new legislative framework considering the approach for marketing of products”. They deal with existing market surveillance systems for industrial goods and import controls. The stakeholder’s proposals refer to the so called CE-marking. As this mark can be obtained by following a certain procedure set up in modules, stakeholders (mostly SMEs) claim disproportionate difficulties complying with these rules. Stakeholders suggest that certain types of SMEs should be exempted from the obligation to equip their products with the CE mark or to limit examination requirements to module A. The Commission disagrees with the possibility of exemptions from CE-marking for SMEs as this will counter the principles of free circulation of goods. It points out that the new legislative framework (adopted in 2008 and currently under implementation) provides for the flexibility required by SMEs without compromising on the protection of public interest. *The HLG asks the Commission to ensure that the implementation of the new legislative framework takes the particularities of SMEs duly into account. Besides, the Group asks the Commission to make sure that external controlling does not lead to the demand of unnecessary information. Therefore, the HLG calls upon the Commission to encourage Member States to use their discretionary authority in order to avoid the demand for unnecessary burden for the economic operators. The HLG recommends the use of module A in situations where this does not affect the high level protection of the public interest.*

IV. Conclusions

- (27) *The HLG takes note of the suggestions made by stakeholders and encourages the Commission to take a proactive approach, as specified in the HLG’s conclusions on the suggestions above. The HLG would appreciate to be informed about the steps taken by the current Commission before the end of its mandate.*
- (28) *The HLG stresses the importance of common efforts to reduce administrative burden for businesses. These efforts must be extended and intensified both on the European and the national level, in order to reach the target of reducing red tape in a sustainable manner.*
- (29) *The HLG welcomes the active involvement of stakeholders. The HLG is of the opinion that many suggestions reviewed by the HLG prove that stakeholders have a vital role to play in the process of making European legislation less burdensome for business. The suggestions made by stakeholders should be taken as an incentive for new initiatives as well as an opportunity for the Commission to broaden existing initiatives to reduce red tape.*
- (30) *The HLG signals that some of the stakeholder suggestions dealt with in this opinion fall outside the scope of the Action Programme. Sometimes proposals refer to administrative burdens in legislation that is not measured, or refer to other costs that are not included in the definition of administrative burdens. In view of the HLG Better Regulation requires a mindset where all these efforts of stakeholders are seriously taken into consideration, and it asks the Commission to ensure an adequate follow-up.*
- (31) *The HLG is aware that for meeting the reduction target of 25 % it is crucial to keep the process going. Therefore, the HLG would appreciate more information from the*

Commission on the further proceedings of the stakeholders' suggestions including the selected suggestions and the HLG conclusions on these.

Brussels, 7 July 2009

Annex A: Overview of the suggestions