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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Regulation No 11 concerning the abolition of discrimination in transport rates
and conditions, in implementation of Article 79 (3) of the Treaty establishing the
European Economic Community and Regulation (EC) No 852/2004 of the European
Parliament and the Council on the hygiene of foodstuffs**

**Impact assessment
(Regulation 852/2004 Food hygiene - Hazard Analysis
and Critical Control Point requirements)**

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Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation No 11 concerning the abolition of discrimination in transport rates and conditions, in implementation of Article 79 (3) of the Treaty establishing the European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Impact assessment

(Regulation 852/2004 Food hygiene - Hazard Analysis and Critical Control Point requirements)

1. PROBLEM DEFINITION

Regulation (EC) No 852/2004 on food hygiene lays down that all food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. This entails the following activities:

- ∄ Identify hazards,
- ∄ Identify critical control points to prevent or eliminate hazards,
- ∄ Establish critical limits at critical control points,
- ∄ Establish and implement monitoring procedures at the critical control points,
- ∄ Establish corrective action when a critical control point is out of control,
- ∄ Establish procedures to verify that measures are working effectively,
- ∄ Establish documents and records to demonstrate application of the above.

To be applied properly, the obligation to implement HACCP procedures requires a multidisciplinary team of staff that is capable of identifying hazards, identifying critical control points, establishing critical limits, establish monitoring procedures at the critical points etc. Businesses are also required to establish documentation for backing-up the procedures and keep records. These requirements entail significant annual costs at EU-level (estimated at € 220.000.000¹), although bigger businesses may consider these costs marginal because for them they represent a smaller proportion of overall costs. However, for smaller businesses (SMEs) these requirements prove extremely costly and burdensome (as evidenced by the stakeholder consultation and the analysis contained in the guidance document quoted

¹ Figures from the measurement of administrative burdens in Denmark have been extrapolated to the EU-level based on the relative percentage of GDP (World Bank data, 2005) and the country distribution list developed by Kox (2005) in order to correct the extrapolated figures according to different estimated levels of administrative burdens in different Member States. However, this figure states the estimated total administrative cost at EU-level and not necessarily the reduction potential.

hereunder). From the time of adoption of the Regulation, representatives of small businesses have expressed their concerns with regard to the general implementation of the HACCP system in all food businesses. Whilst the Regulation has some flexibility, analysis shows that clarification is necessary.

The Commission's Health and Consumer Protection Directorate General held a series of meetings with experts from the Member States in order to examine and reach consensus on these issues.

In addition, and in the interest of transparency, the Commission's Health and Consumer Protection Directorate General promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end a meeting with representatives from producers, industry, commerce and consumers was organised to discuss issues related to the implementation of HACCP based procedures and to HACCP flexibility.

The results of these discussions are laid down in a guidance document that was endorsed by the Standing Committee of the Food Chain and Animal Health. This document is available via the following link:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Due to the significant impact on SMEs that a strict application of the HACCP requirements would lead to and the fact that some businesses can provide the same level of hygienic protection by implementing all the other requirements of Regulation (EC) No 853/2004, without there being a need to implement fully fledged HACCP procedures and despite a guidance document explaining the extent to which flexibility can be applied with regard to HACCP, there is a need for an exemption for some enterprises from all the HACCP requirements. The exemption should therefore be limited to businesses with fewer than 10 employees which can be classified as micro-enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

Although Member States participated in developing the guidance document and agree on the principles, there is significant uncertainty regarding whether businesses actually do benefit from this new guidance as it is not being applied evenly across Member States and as it is not legally binding. This leads to unequal treatment of food businesses, with some SME food businesses being disadvantaged. In addition, there are questions concerning legal security for the above mentioned establishments when following the guidance document. In summary, the present situation leads to unnecessary information obligations being maintained *de facto*.

2. OBJECTIVES

The main objective of this initiative is to contribute to the Lisbon strategy for growth and jobs, in particular by reducing the costs of doing business for certain SMEs in the food sector. The operational objective in this case is to ensure that information obligations do not disproportionately affect the day-to-day running of a business and that they are not disproportionately costly. In this particular case it is to assess whether there are ways in which the burden on SMEs in the food sector can be eased while maintaining the same adequate level of health protection.

As the objectives are to reduce the administrative burden on business and the improvement of EU competitiveness, while preserving levels of protection, they are fully consistent with the Lisbon strategy and the Sustainable Development strategy.

3. POLICY OPTIONS

Given the objectives stated above, the scope for some firms to a possible exemption from the HACCP requirements must be based on the capacity of the food business to control food hygiene and to deliver food hygiene results by implementing good hygienic practices that are at least equivalent to those currently achieved by adhering to the HACCP requirements. Otherwise the current obligations should not be relaxed at all. Thus, the following policy options lend themselves to further examination:

Option 1 No-Policy Change

This options means that the existing Regulation is unchanged and that no additional steps are taken in addition to the existing guidance which is mentioned in the Problem Definition above.

Option 2 Exempting certain businesses from the HACCP requirements

This option involves exempting certain businesses from the HACCP requirements as long as it can be guaranteed that they can meet the same food hygiene standards as if they applied all the HACCP requirements. This means that the same level of protection needs to be ensured by adhering to the other requirements laid down in Regulation (EC) No 852/2004, whether or not completed with guides to good practice, and called "prerequisite requirements". The guidance document referred to above already identifies that by having "prerequisite" food hygiene requirements in place, some businesses can achieve the same level of protection. The businesses to be exempted are micro-enterprises with less than ten employees predominantly selling food directly to the final consumer without processing the food. The exemption does not apply to large surface supermarkets and franchisers of supermarket chains.

It is unlikely that in the course of their work the exempted businesses add new hazards to food that must be controlled by implementing HACCP procedures. If new hazards emerge from handling food in these businesses, they can be controlled by implementing non-HACCP control measures.

Option 3 Abolition of HACCP procedures for all businesses

Under this option HACCP procedures for all business in the food sector would be abolished.

4. ANALYSIS OF OPTIONS

Option 1

Under this option the current situation would not change. The seemingly high level of consumer health protection would be maintained and standards and procedures that are required for meeting those standards would be the same across the food sector. This would imply that SMEs would continue to face significant costs to meet existing information requirements. The guidance document mentioned above could offer some smaller businesses

an exemption but the current problem with regard to implementation and particularly the legal uncertainty would persist since the guidance document is not enforceable. Member States may prefer not to implement these solutions or to impose different solutions thus leading to unequal treatment of food businesses.

Option 2

Exempting micro-enterprises as stated above from the HACCP requirements that were mentioned above in the Problem Definition section would have a real impact on their day-to-day running and allow them to become more efficient. However, any such exemption must not come at the expense of lowering hygiene standards. In food businesses such as small retail outlets selling their products directly to the final consumer, e.g. bakeries, grocery shops, market stalls, fish retail shops, restaurants, and bars, food hygiene can be ensured by complying with all the other requirements of Regulation (EC) No 852/2004, without having to implement the HACCP system.

It should be pointed out that *'HACCP systems are not a replacement for other food hygiene requirements'*² rather they are one element of a integrated and wide ranging strategy that provides for food safety. Before establishing HACCP procedures 'prerequisite' food hygiene practices must already be in place. In particular, these prerequisites are:

- Infrastructural and equipment requirements,
- Requirements for raw materials,
- The safe handling of food (including packaging and transport),
- Food waste handling,
- Pest control procedures,
- Sanitation procedures (cleaning and disinfection),
- Water quality,
- Maintenance of the cold chain,
- The health of staff,
- Personal hygiene,
- Training.

These so-called prerequisite requirements are aimed at controlling hazards and are clearly prescribed in Community law. Furthermore, there are other Community law based requirements such as traceability (Article 18 of Regulation (EC) No 178/2002) and on the withdrawal of food and the duty of informing the competent authorities (Article 19 of Regulation (EC) No 178/2002) that could, although not covered under the food hygiene rules, also be considered as prerequisite requirements.

² See page 18 of the guidance document
http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Where there is no processing, manufacturing or only limited preparation of food, such as the slicing of food, good adherence to and correct application of the prerequisite requirements produces the same levels of hygienic protection that HACCP practices do. This is especially the case where sector specific guides exist that complement the Community law based prerequisite requirements, for example, for operators in the restaurant and catering sectors. In other words, where these things are in place the additional benefit from implementing all HACCP requirements is not given.

According to the estimates presented above, the annual costs of these requirements are approximately EUR 220 million. These costs will obviously be significantly reduced by exempting certain businesses from the requirements as companies will have to spend less time on administrative activities.³ However, giving a precise estimate of the total administrative burden savings is fraught with difficulty at this stage. The EUR 220 million estimated annual costs are likely to contain some compliance costs (sunk costs) that strictly speaking cannot be counted towards the administrative burden. The final reduction of the administrative burden will depend on the number of businesses eligible for the exemptions from the HACCP requirements and the amount of the annual cost estimate that forms the administrative burden element. The Commission will produce more concrete data on these aspects in due course.. Once that is available, a better estimate of the contribution this proposal can make towards the overall 25% reduction target will become available.

It is not excluded that other businesses could also be exempted from the systematic implementation of HACCP procedures at a later stage, in particular those businesses that process food in accordance with standard practices for which experience has shown that they ensure the safety of food. However, this will require an in-depth analysis and further consultation and discussion. It is suggested that such analysis is undertaken under the review that is to be undertaken by virtue of Article 16 of Regulation (EC) No 852/2004, not later than 20 May 2009.

Option 3

If this option was followed all HACCP requirements for all food businesses would be abolished. It is mentioned above that there is evidence based on experience that shows that those companies mentioned in option 2 could offer the same level of hygiene by following normal hygiene procedures. The same however does not necessarily apply to the big food industry, particularly if it involves food processing. Hence, while a wider ranging exemption would generate more significant savings (EUR 220 million); it would also risk lowering food hygiene standards and could, therefore, be at odds with one of the main objectives of the Administrative Burden reduction exercise.

5. COMPARING THE OPTIONS

Option 3 risks not fulfilling the fundamental objective of not lowering standards. Option 1 would not change the status quo, meaning the legal uncertainty regarding the existing guidance would persist and smaller businesses in several Member States would continue to incur unnecessarily high costs. Option 2 seems to offer the best way forward by combining exemptions for micro-enterprises predominantly selling food directly to the final consumer

³ It is not possible to assess the exact number of businesses that would be exempted by this option. Therefore, it is not possible to estimate expected savings at present.

and significant reduction of the administrative burdens with maintaining the same food hygiene standards. It should be stressed that the available evidence indicates that food hygiene standards would not be lowered and that therefore these estimated cost savings are not offset by other impacts.

6. MONITORING AND EVALUATION

Member States and trade associations would be asked to communicate the exemption to businesses concerned, but it would be disproportionate to collect data at EU level on how many of the businesses that are eligible for the exemption would use it. Any lingering health and safety concerns would be picked up by existing food hygiene monitoring provisions.

As mentioned above, the baseline measurement exercise will produce more concrete data regarding the actual administrative burden reduction that this proposal is going to lead to.