

SUPPORT TO THE DECISION OF DG HEALTH AND FOOD SAFETY (SANTE) OF CREATING A WORKING GROUP ON FLEXIBILITY AT EUROPEAN LEVEL

Since the entry into force of the European Hygiene Regulations (The Hygiene Package), in several times, both the level of implementation and the development of flexibility in different Member States (MS) have been checked.

Of particular importance is the *“General Report of a mission series carried out in six Member States in the period November 2009 to March 2010 in order to gather information regarding the application of the hygiene regulations in small establishments producing meat and meat products of mammals and dairy products (DG(SANCO)/2010-6150 - MR FINAL)”*. Some important conclusions are:

1. When applying flexibility provisions, the **majority of the MS visited had not notified one or more national measures as required and also in relation to national measures for food with traditional characteristics (simple information)** cases were seen where **no information about the national measure had been notified** to other MS and to the Commission services.
2. Regarding national measures requiring notification prior to adoption of these measures, it could be seen that **national measures introduced through law were usually notified whereas national measures that were only contained in national implementing provisions or guidelines occasionally were not notified.**
3. A number of **national measures** have been introduced which **possibly affect the achievement of the objectives of the Hygiene Regulations.**
4. It were identified some **compliance issues** in different areas which **could have been addressed appropriately by providing flexibility** to small establishments, for instance: separation in time of different activities carried out in the same place, the availability of changing rooms, the access from changing rooms to working rooms, temperature registration, the requirement to establish HACCP-based procedures, sampling program in relation to potable water.
5. Of special importance is the **obligation for double testing of raw milk for antibiotics** – in the first establishment and in the second where the raw milk was however only processed after the result from the first establishment became available-, and the **antibiotic testing of the milk** processed in a dairy establishment **using only the milk from its own farm.**

6. Establishments and their operations showed **more deficiencies where national measures for flexibility were not available**. In the **small establishments** visited, which **could not benefit from flexibility measures, noncompliance was more frequent**.
7. **The level of application of flexibility measures was very different in the six MS visited**: whereas some MS had made use of many flexibility provisions other MS had only made very limited use of flexibility measures.
8. In some MS the **flexibility measures applied were different between the regions** and the **Central Competent Authority was not always aware** of the details of the flexibility measures applied in all parts of the MS.
9. Sometimes, it was **solely left to the local authorities to apply flexibility at local level** using the provisions already provided in the Hygiene Regulations **without adoption of additional national measures**.
10. In some MS visited the **measures provided for** seem to **go beyond the provisions currently foreseen** in the Hygiene Regulations.

According to these results, the Commission **recommends to introduce flexibility measures more widely and to encourage their implementation**.

For this purpose, several guidance documents on the application of flexibility procedures for the Competent Authorities and Food Business Operators have been published with the aim of improving and encouraging adaptation of the hygiene package to the reality of small enterprises, including farmhouse and artisan cheese makers.

At the request of FACE-Network, The Commission has promoted several editions of BTSF (Better training for safer food) training courses for official inspectors on the implementation of flexibility criteria.

Despite all this, at the present time, we can state the following facts:

1. **Many noncompliances** can be found in **small food businesses** regarding the hygiene regulations. This does not necessarily mean that unsafe food is being produced.
2. **Limited knowledge** about possibilities for **flexibility** in the hygiene regulations is common between **Competent Authority** and **official inspectors**.
3. Sometimes, a **negative response is given from the competent authorities** when they are **asked to address the development of criteria for flexibility in small food businesses**.
4. It's common to find that **official inspectors** assume the responsibility for "**granting**" the **exceptions and adaptations** on the application of the hygiene package. We are aware that this **does not follow the established procedure** and can cause further

discrimination of some food businesses, depending on the **will of the official inspector**.

5. There are cases where the **development of national flexibility measures** has resulted in **more strict and inappropriate requirements**. As a result there has been a **non compliances increase in small food businesses**.
6. Despite the effort made by some competent authorities and food business sector, the **current national guides to good practice** are **not solving the difficulties** of application of Community Regulations **to small food businesses**.
7. **The facts found by the different EU missions** as stated in the mentioned reports, **have yet to be addressed and solved by the Competent Authorities**.

For all these reasons, we deeply welcome the decision, recently expressed by a representative of DG Health and Food Safety (SANTE), of creating a specific working group on flexibility, at the European level, led by DG SANTE.

We strongly support this idea in order to achieve the following objectives:

- a) **Assess the flexibility granted** in the application of the European Hygiene Regulations in all Member States, **identifying** those food sectors, kinds of businesses, food and aspects of the legislation, in which **the lack of flexibility or poor implementation are hampering the development thereof**.
- b) **Identify those non conformities found by the official inspectors in the food businesses** of all Member States, which do not affect food safety and **could be resolved applying flexibility procedures** by the competent authorities.
- c) **Advise, assist and coordinate** the different **Competent Authorities** of Member States, for a **better and uniform development of flexibility procedures** in the hygiene package.
- d) **Advise and collaborate** with representatives of **food sectors** for a better application of flexibility on those hygiene regulations aspects that depend on them (HACCP based procedures and some requirement aspects for premises and equipments, among others)
- e) **Monitor and verify** that the **application of flexibility procedures** by Member States **does not go beyond the provisions** currently foreseen, and that it is conducted **according to the established procedures**.
- f) Hold regular **meetings with representatives of small food industry, related professional organizations and NGOs**, to report on **progress made** on the application of flexibility, and **exchange opinions and proposals**.
- g) **Collaborate in any other task or objective demanded by the Commission**.

We congratulate the Commission for the implementation of this new initiative that aims the preservation of the small-scale enterprises, and we express our determination of being an active part of this working group.

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