

EC Draft Regulation establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food

Response to the Draft Motion for a Resolution pursuant to Rule 106(2), (3) and (4)(c) from MEP Elisabeth Köstinger

1. The EC's proposition in accordance with the implementing powers provided in the basic act and specifically the HACCP principles

The implementing competences of the Commission with regards to the *draft regulation establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food* are laid down in the basic act: **Regulation (EC) No 852/2004**.

Article 5 of this Regulation refers to the **HACCP principles** (Hazard Analysis Critical Control Point) which bind food business operators (FBOs) to take any measures necessary to prevent, eliminate or reduce to acceptable levels whatever hazards that might occur at any stage of production, processing and distribution of food. Moreover, FBOs are also bound to provide the competent authority with evidence of their compliance with the HACCP principles. Indeed FBOs are responsible for ensuring the effectivity of food safety (Recital 8).

To help FBOs to put the HACCP principles into practice, the Commission, assisted by the Standing Committee on the Food Chain and Animal Health, **is competent to elaborate detailed arrangements (Article 5.5)**.

Consequently, the Commission is entitled to provide FBOs with mitigation measures for the reduction of acrylamide concentration in foodstuffs.

2. The necessary intervention of the EU to achieve an effective reduction of acrylamide levels in foodstuffs (compliance with the principle of subsidiarity)

The **principle of subsidiarity (Article 5 TEU)** aims at determining when the EU is competent to legislate by determining the level of intervention that is most relevant in the areas of competences shared between the EU and the EU Member States.

With regards to reducing the presence of acrylamide in foodstuffs, since 2011, Member States are only required to carry out investigations on the production and processing methods when the concentration of acrylamide in food exceeds the

indicative value¹. Nevertheless, the investigation means put into place by Member States are far from sufficient and demonstrate that the implementation of voluntary-basis measures to reduce acrylamide in foodstuffs by FBOs are unsuccessful. **Consequently, the EU's intervention would be more effective than the current self-regulation system.**

In her opposition MEP Elisabeth Köstinger questions the connection between the acrylamide concentration in blood and nutrition based on the research of the Hannover Medical School (Recital E). Yet, this research has been criticized by its peers because it was based on participant's memory of what they ate during the past 3 months, which, as confirmed by Jürgen Angerer (University of Erlangen-Nuremberg), is not a reliable method².

In addition, the Scientific Opinion on Acrylamide in Food conducted by EFSA Panel on Contaminants in the Food Chain published on the 4th of June 2015³ has shown that dietary exposure to acrylamide may increase the development of cancers. **Acrylamide concentration in food being a matter of human health, it is thereby a transnational issue that has not been resolved by EU countries.**

Indeed, significant deficiencies are identified in the current self-regulation system regarding this matter given that acrylamide concentration in food products has not been reduced significantly over the years. The Scientific Report of EFSA "Update on acrylamide levels in food from monitoring years 2007 to 2010" published on the 23rd of October 2012⁴ show that **there isn't a consistent downward trend in many food products, there is even an increase in certain products** such as potato crisps, wafers and biscuits. In order to compensate for this lack of legislation, some food business operators (FBOs) have, on a voluntary basis, adopted some codes of good practices. However, despite these initiatives voluntary basis mitigation measures are not sufficient to notably decrease the concentration of acrylamide in foodstuffs.

Consequently, the current self-regulation system is inadequate to ensure a high level of human health protection which should be ensured according to the **Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU).**

Furthermore, allowing Member States to self-regulate the levels of acrylamide in foodstuffs may also lead to significant differences between the national legal systems and thereby **putting barriers up to the free movement of food products as governed by Article 26 of the TFUE.** Unlike what MEP Elisabeth Köstinger asserts in her opposition (Recital Q) harmonization of the mitigation measures intends to

¹ Article 1(1), subparagraph a(3), Commission Regulation (EU) No 420/2011 of 29 April 2011 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

² Acrylamide study sparks German debate, *The Scientist*, 5 November 2005: [<http://www.the-scientist.com/?articles.view/articleNo/23504/title/Acrylamide-study-sparks-German-debate/>]

³ Scientific Opinion on Acrylamide in Food, EFSA Panel on Contaminants in the Food Chain, 4 June 2015: [<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4104/epdf>]

⁴ Scientific Report of EFSA, Update on acrylamide levels in food from monitoring years 2007 to 2010, 23 October 2012: [<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2938/epdf>]

remove such differences and barriers and thus allows fair competition in the single market.

In light of the foregoing, a regulation at EU level would be more efficient to decrease acrylamide concentration in foodstuffs than the current self-regulation system and to achieve the European Union's objectives of ensuring a high level of human health protection and the proper functioning of the internal market.

3. Differentiation between small and large FBOs ensuring the respect of the principle of proportionality

Having regard to Article 5.4 of the TEU, the means, content and form of action implemented by the Draft Regulation to meet the objectives set by the Treaties cannot go beyond what is necessary.

Regulation (EC) 852/2004 under which the Draft Regulation lays its mitigation measures, provides the requirements regarding the hazard control and measures to protect food products from contamination. The latter lays down measures regarding the preparation, storage, use and traceability of feed for FBOs to implement. An information and awareness campaign on the presence of acrylamide in foodstuffs, as mentioned by MEP Elisabeth Köstinger in her opposition (Recital H), is already highly encouraged by the EC⁵, specifically to inform consumers on the matter. Nevertheless, an awareness raising campaign needs to be accompanied with binding measures to reduce the levels of acrylamide in food products. The lack of significant decrease of acrylamide levels in food under the self-regulation measures (further explained in point 2) shows the necessity to establish thresholds and monitoring programmes, such as sampling, to ensure that EU consumer's health remains the principle guiding the future legislation. Furthermore, by differentiating large FBOs from small FBOs regarding the measures on sampling, analysis and preparations, the Draft Regulation does not go beyond what is necessary to achieve the objectives set by the Treaties and the basic act. Consequently, it does not generate an excessive bureaucracy nor an enormous burden for small FBOs such as bakeries and restaurants.

a. Soft mitigation and preparation measures for SMEs

The Draft Regulation clearly distinguishes Food Business Operators according to their size:

- Largest FBOs and major brands (Article 2.1);
- FBOs who perform retail activities and/or supply only local retail establishments (Article 2.2);

⁵ [<http://www.keithtaylormep.org.uk/wp-content/uploads/acrylamide-response.pdf>]

- FBOs who perform retail activities but are part of franchises or larger conglomerates (**Article 2.3**).

This size differentiation was made to take into consideration the difference of capabilities and resources of FBOs and to **avoid putting an excessive burden on small industries**. Indeed, the category of FBOs mentioned in Art. 2.2 (i.e. bakeries, friteries, restaurants and hotels) have to comply with the mitigation and preparation measures provided for in Annex II Part A. **The latter includes measures which were already part of voluntary mitigation measures developed by the small and large FBOs themselves**. As a matter of fact, SMEs, restaurants, cafés and bakery shops were up to now encouraged to put these measures for managing acrylamide formation in food into practice by following the codes of practice provided by the umbrella associations representing their interests at EU level (i.e. AIBI, HOTREC, EUPPA).

Furthermore, several provisions of the Regulation which could be unwieldy, impractical or burdensome for small FBOs such as soaking or blanching French fries before frying (Annex II, Part A, Article 1) or extending the yeast fermentation time and lower the oven temperature for fine bakery products (Annex II, Part A, Article 2) **are tempered by a condition of feasibility within the production process**.

Having regard to **Article 1.1(a) of the Regulation (EC) 852/2004** « primary responsibility for food safety rests with the food business operator;”. The latter does not differentiate between small and large FBOs and **places the responsibility to all operators in ensuring food safety of their products**.

b. Exemption of SMEs from sampling and analysis measures

Sampling and analysing the levels of acrylamide in food products are necessary measures to ensure compliance with the provisions of the **Regulation (EC) 852/2004 on the hygiene of foodstuffs - Recital (12)**.

Furthermore, the application of HACCP requirements “**should provide sufficient flexibility to be applicable in all situations, including in small businesses**” (recital 15). Indeed, the Draft Regulation considers the capabilities and resources of FBOs by **exempting fully small FBOs from the sampling and analysis requirements (Art. 4.6)**. Thus, small business operators are only required to apply the simplified mitigation measures listed in Annex II Part A. The latter provides **simple requirements regarding the storage and handling of foods**. The flexibility of hazard analysis and control is also applicable for large FBO. Indeed, Annex III. I). (1) offers the **possibility to replace the analytical tests by the “measurement of products attributes”** such as visual checks, and thus considerably reducing paperwork for FBOs.

It is important to stress that the sampling and analysis of the levels of acrylamide in foodstuffs is not made for the purposes of sanctioning FBOs but to **ensure a consumer’s exposure to the carcinogen contaminant to consistently stay below the benchmark levels** referred to in Annex IV of the Draft Regulation.