The EU and your Product – A Case Study:
Be aware of the great benefits but also the dangerous pitfalls of harmonization.

Introduction

Roughly, about 80% of the legislation that covers food and beverage products placed in the 28 EU Member states is covered by EU legislation. There are areas where national governments retain overall competence (the use of plants and other substances such as glucosamine in food supplements) for example, but these are increasingly limited. For that reason, remaining abreast of the ever changing regulation which applies to a company's key ingredients and labelling rules is important. However, awareness of what is going on is just the first step, understanding how to have an impact and how to influence regulation that affects your business is essential in ensuring that you can be proactive rather than reactive in today's competitive market environment.

Harmonization allows products to flow freely between Member States and is one of the **key economic benefits** of the EU. However, given that each EU Member State has its own historical regulatory approach and culture, harmonization **is not an easy process** and is not always appropriate. Simply put, **harmonization done well delivers great market opportunities, jobs and growth, but done badly, it can endanger companies and jobs**. Ensuring it is done properly, is in the interests of companies active in the EU and is the primary function of trade associations representing various industry sectors in Brussels.

This blog looks at the example of re-evaluation of the **General Food Law Regulation (EC)** 178/2002 (the GFL). The GFL is the cornerstone of EU regulation governing the entire foodchain. Established in 2002, the GFL was recently placed under evaluation.

What does this mean for your business?

This means that the European Commission were mandated to carry out an evaluation on whether GFL was functioning correctly. The figure below shows the regulatory process which typically occurs in the case of legislation. That is, the European Commission carries out an evaluation and proposes legislation. This can be a proposal for new legislation or an amendment to existing legislation that is considered to be functioning ineffectively. The proposal is then considered by the European Parliament and the Council of Ministers where amendments can be developed. However, the figure below only illustrates the process without the involvement of industry.

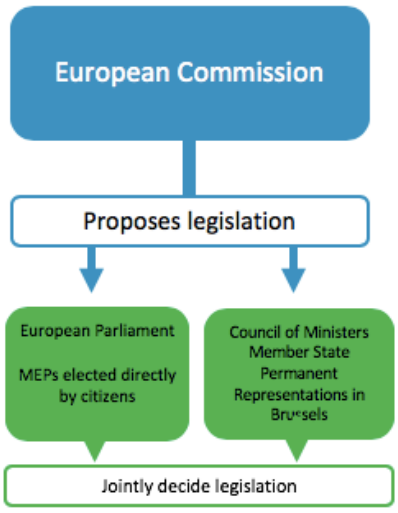


Figure 1: Overview of the legislative process, Source: EHPM, 2017

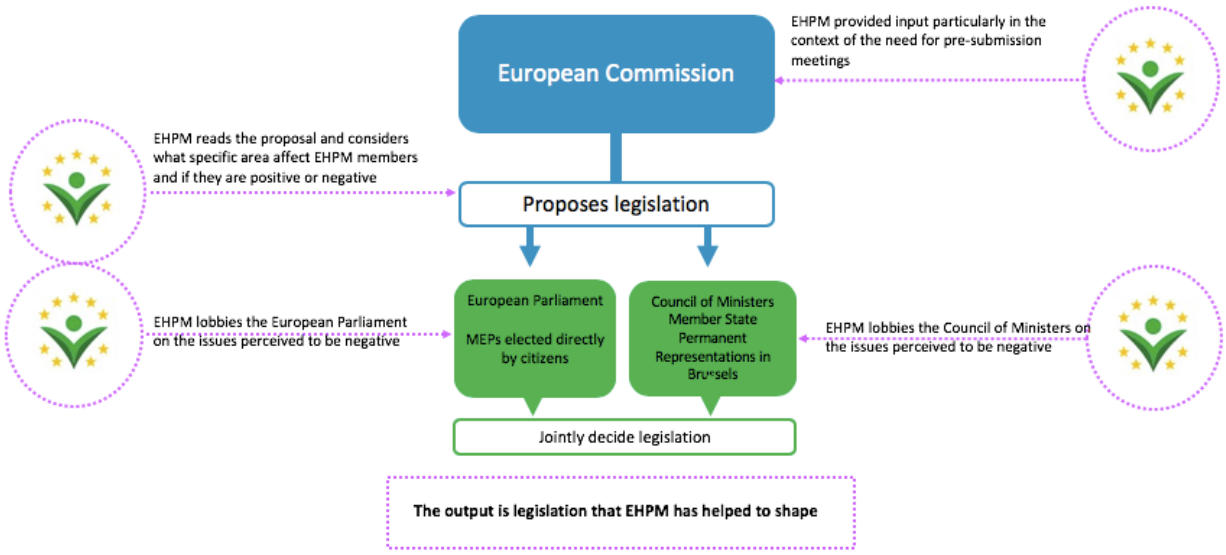
How to use the process to support your business: The GFL example

The role of industry in this process occurs at multiple stages and is essential to ensuring the legislation takes into account the real issues faced by businesses and puts forward regulation that promotes fair competition. During the later part of 2017, industry submitted contributions to support areas for improvement in relation to the GFL. Contributions differ between different sectors (dairy, food supplement industry, pesticides etc.), but consist of areas that are significant for specific businesses. For example, EHPM emphasized strongly the need for pre-submission meetings between the European Food Safety Authority [EFSA] and applicants (for health claims, novel foods etc.) as did the UEAPME the European SME umbrella group of which EHPM is a member. The proposal ultimately put forward by the European Commission did include a provision for pre-submission meetings albeit one that needs to be significantly strengthened – see more detail below. In the GFL law review, a lot of emphasis is being placed on the importance of the evidence submitted to EFSA being published, to facilitate more transparency in the assessment process. This is due to the controversy surrounding the recent renewal of the approval of the pesticide glyphosate

What does the pre-submission example show?
There was broad industry agreement across multiple sectors on the need for pre-submission meetings. The Commission did propose pre-submission meetings but stipulated that these would only be with EFSA staff and not the relevant EFSA scientific panel and that the meeting would not cover clinical trials. In the case of applications where companies are seeking permission to claim a specific health benefit on labelling, clinical trials are the key piece of evidence sought by EFSA. Experience has shown that to have any chance of success, 3 trials are needed that cost in the region of €1.5 million. Up to now, despite huge investments in clinical trials, about 95% of applications have been rejected. One of the main reasons for rejections cited by EFSA has been the inadequacy of different elements of clinical trials. Nevertheless, EFSA refuses to discuss trial design with applicants in advance, relying on providing written guidance that is clearly inadequate given the huge rejection rate. By contrast, pharmaceutical companies seeking to secure the approval of a medicinal product are free to discuss the various requirements with the European Medicine's Agency. EFSA, with the support of the European Commission refuses to engage in a similar process on the basis that it would compromise the integrity of those accessing the applications.

Surely, all sectors applying for different types of products/ingredient approval under EU legislation should be treated the same? The example above shows this is not case. It should not be automatically assumed that all sectors are treated the same. On the face of it, procedures are in place to allow all interested parties have their say on any policy issue but in reality, the amount of money invested in lobbying and the level of public visibility on the issues under discussion directly impact on the legislative and regulatory outcomes. In the case of pre-submission meetings, the European Commission indicated that the proposal it made was specifically designed to meet the requirements of SMEs, such as those represented by EHPM. However, the reality is that for the food supplement sector, **a pre-submission meeting where you can't discuss the design of clinical trials is about as useful as an umbrella with a hole in it**.

Fortunately, the nature of the process for adopting legislation at EU level allows for affected parties to seek support from Member States governments and the Members of the European Parliament to improve where necessary proposals from the European Commission. The figure below now shows the legislative process with the inclusion of industry contribution and lobbying.



Amendments to the European Commission's proposal more favourable, but not there yet.
On the 10th of July, 2018, amendments to GFL proposal by the MEP responsible for developing the European Parliaments position were put forward. These addressed some of the issues that had the industry on high alert, however more action is needed before the Parliament finalizes its position on the Commission proposal in November. One amendment in particular (25) addresses to some extent the need for a meaningful pre-submission process that allows applicants to discuss the requirements for clinical trials. The requirement for evidence supporting applications to be published remains controversial, as the need to protect sensitive commercial information linked to innovation, while at the same time ensuring sufficient transparency is a tricky issue.

The outcome of the GFL law review remains pending but we will be able to share more updates with anyone interested if you visit our stand at HI Europe 8E25.

Maximise your involvement to maximise opportunities for your product
The European food supplement sector is comprised mainly of SMEs and as such there is a limited budget available to invest in applications that do not support fair competition in the marketplace. Ensuring that you are involved at the different stages of the legislative process provides your business with the opportunity to have your concerns heard and allows your company to help contribute to and shape new and evolving legislation.