AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

REFIT of the General Food Law

Tackling transparency and sustainability of risk assessment in the food chain

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2017, directly supports more than 4.7 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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Executive summary

Key messages:

- We **welcome the Commission proposal** on the transparency and sustainability of EU risk assessment in the food chain and supports its work to better address public perception of the EU risk assessment process, and to improve risk communication.

- We believe that increasing transparency in the EU risk assessment process can contribute to strengthening public trust in the system. However, **it is important to strike the right balance between ensuring transparency and protecting confidential and legitimate business information,** which is essential in guaranteeing innovation, promoting investment and ensuring the competitiveness of the EU food sector.

- We believe that **more emphasis should be placed on risk communication,** and that the type and level of communication activities needed to address consumer needs appropriately should be improved.

- We also believe that the European Commission and Member States must increase their efforts to strengthen risk management activities in order to achieve wider consumer confidence.

Our position

Societal expectations regarding public health and policy making are rapidly changing and the American Chamber of Commerce to the European Union (AmCham EU) recognises the legitimate public demand for greater transparency in EU evaluation procedures.

Risk Assessment

We welcome the efforts of the European Commission and the European Food Safety Authority (EFSA) to strengthen trust in the EU risk assessment model across the EU food and feed chain. This requires a holistic approach, ensuring both the sustainability and transparency of the risk assessment and risk management processes, supported by consistent decision-making of risk managers, and improved risk communication from the European Commission, EFSA and EU Member States.

We support the Commission's intention to provide greater public access to information and the studies underlying EFSA's risk assessments. We believe, however, that the timing of disclosure of confidential business information (CBI) at the start of the risk assessment process, and easy accessibility combined with no clear and enforceable rules against commercial misuse, could enable fraudulent activities at a global level; other players could use this data to support product registration in third countries or even worse, encourage counterfeiters. This would create a huge issue for global companies involved in product development, due to the lack of protection of regulatory data in countries outside of the EU. Adequate and enforceable sanctions for misuse should be included in the proposal. Insufficient protection of regulatory data and misuse thereof for commercial purposes threatens innovation, investments and jobs in the EU and beyond.

Risk Communication

Despite ensuring high levels of public safety, the current system is not well communicated or understood by the public at large. In the Commission's roadmap document linked to this initiative they state that: "Risk communication is, overall, considered not to be effective enough, especially in light of the difficulty of communicating science-based risk assessment decisions in an environment characterized by increasing scepticism about the objectivity of scientific findings".

The proposal attempts to address the challenges around risk communication by setting out a framework of the objectives and general principles that it should pursue and comply with. However the current proposal leaves the drafting of this framework for later, to be adopted and implemented via secondary legislation. We would encourage the Parliament and Council to place stricter timelines on the Commission to do so, or even consider additional criteria for consideration in the basic act. Leaving it fully in the hands of the Commission in its capacity as risk manager may take too long and may not achieve the shared political and technical objectives of all institutions and parties. It is clear that a lot of work needs to be done on the side of the Commission and EFSA to improve the type and level of communication activities needed to address their consumers.

As the main objective is to enhance coordination between EU and national risk assessors, to achieve effective communication to the public, we support the effort to strengthen risk communication on issues relevant to the agri-food chain. We consider that there must be a big step change in the communication intended to address the broader public. Therefore, we deeply regret that the Commission has not proposed any actions to combat the spread and sources of misinformation, particularly those that severely undermine science-based risk assessment and the credibility of EFSA. If misinformation is allowed to flourish and spread, science-based risk assessment and the credibility of EFSA and national risk assessment authorities will continue to be undermined.

The other actions outlined in the Commission's initiative, aimed at increasing transparency, are unlikely to improve public confidence and understanding of the regulatory process alone, unless supported by better and clearer risk communication. More effective risk communication will require improved cooperation between risk assessors and risk managers at both EU and national level, but this should not compromise the independence of risk assessors, and should be accompanied by a clear risk management perspective. Improved communication should strive to highlight the integrity and quality of EFSA's scientific opinions in an understandable, timely, and coherent manner. It should also be tailored to address public perception on topical issues ('hot topics'), and involve all stakeholders from the outset to ensure maximum dissemination and leadership at national and EU level. Quality, comprehensibility, lucidity and relevance of information that can be easily understood by EU citizens are more important than quantity.

Conclusion

The strength and robustness of the current system should be communicated to increase both understanding and trust in the risk assessment process as well as the broader decision-making processes. Additionally, AmCham EU believes that future risk communication should take into account both the innovation principle and the precautionary principle, whilst avoiding abuse of the precautionary principle. This means recognising that innovation provides benefits and that the absence of innovation includes risks.

The Commission and other EU institutions have a steep challenge ahead of them, in their efforts to improve transparency and communication around the EU risk assessment and risk management processes, while also endeavouring to effectively combat the spread and sources of misinformation. A collective effort needs to be made to concretely address the sources of unscientific information, their business models and funding sources.

Annex I: WTO rules and protection of legitimate commercial interests

Under WTO rules, the EU has agreed to protect legitimate commercial interests, including CBI. The proposed technical modalities have far reaching consequences (i.e. no legally enforceable undertaking to ensure applicants will not use the information for commercial purposes in any jurisdiction). The Commission proposal would facilitate unfair commercial use of proprietary information in violation of WTO TRIPS Article 39.3, and does not protect the legitimate commercial interests in violation of Annex C (1)(d) of the WTO SPS Agreement. Adequate and enforceable sanctions for misuse should be foreseen in the proposal. Insufficient protection of regulatory data and misuse thereof for commercial purposes threatens innovation, investments and jobs in the EU and beyond.

In order to avoid loss of data compensation[1] in regions beyond the EU and to comply with EU international obligations, including under WTO, it is important to highlight the distinction between the "publication" and "disclosure" of studies as set by the precedent from the EU approach to data transparency in the pharma sector at EMA[2]. Studies should be released via a mechanism of controlled disclosure, and not published. Procedures should also be put in place to ensure that information made available in the EU (which represent a significant investment for applicants) cannot be used for regulatory or commercial purposes in other parts of the world by a competitor and that the EU ensures that sanctions for misuse of such information are enforceable. The level of protection in the EU Commission proposal against such misuse is currently insufficient. A balance needs to be struck between providing greater transparency and access, and the need to protect legitimate confidential business information (CBI) and intellectual property (IP) details. This is essential to fostering innovation and competitiveness in the EU, as well as protecting commercial activities of and trade with foreign companies in the EU and outside of the EU.

[1] Data compensation is a process applicable particularly in the US whereby the data owner of a study is financially compensated by a separate applicant who wishes to have access to the study for the purposes of supporting an application for authorisation.

[2] Website EMA: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000426.jsp&mid

Annex II: Background on the Commission proposal

Following concerns expressed by citizens within the European Citizen's initiative[3], the European Commission issued a proposal to improve the transparency of scientific studies in the food safety area, leveraging the Fitness Check of the General Food Law[4]. This proposal couples a targeted revision of the General Food Law Regulation with some amendments of eight pieces of sectoral legislation including: GMOs, feed additives, smoke flavourings, food contact materials, food additives, food enzymes and flavourings, plant protection products and novel foods.

The proposal aims to:

- give citizens greater access to information submitted to the European Food Safety Authority (EFSA) for approvals across the agri-food chain;
- provide the possibility for additional studies to be requested by the Commission;
- involve Member States' scientists more closely in approval procedures;
- and revise EFSA governance.

After its publication on 11 April, many ministers and MEPs have generally welcomed the proposal, though a number have criticized the absence of an impact assessment, while some others have complained about the tight timeline and the Commission's ambition to rush the new legislation through before the European elections.

Affected industries are concerned that the key elements of the Commission proposal undermine the legitimate interests in the protection of regulatory data, including the effective protection of CBI, both for European and foreign companies doing business in the EU, exporting products to the EU or even conducting business outside of the EU. This raises serious questions of non-compliance with key provisions of EU law and WTO law and can seriously affect the rights and interests of these companies. Nevertheless, this proposal also represents the biggest opportunity to improve EFSA's efficiency and risk communication since it was founded.

[3] http://europa.eu/rapid/press-release_IP-17-5191_en.htm

[4] https://ec.europa.eu/food/safety/general_food_law/fitness_check_en