# Regulatory impact assessment of food safety policies: A preliminary study on alternative EU interventions on dioxins

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## Abstract

Regulatory impact assessment (RIA) for food safety policy interventions faces major obstacles, like scarce data availability and quality, especially when estimating their future effects on consumer health. In this paper, we run a preliminary RIA exercise on alternative EU policy initiatives to address the problem of dioxins in food, through a fuzzy multi-criteria analysis (FMCA) approach. 5 policy options are considered: the status quo situation (non-harmonised and non-efficient application of EU mandatory maximum levels in food and feed across Member States), a regulation imposing stricter (halved) limits, a stricter enforcement of the current regulation, and a co-regulatory version of the fourth option (with industry undertaking their own testing, and public authorities provide auditing and controls in a harmonized effort across all EU countries). A structured qualitative assessment of the considered options is performed regarding 14 categories of potential impacts, with consideration of uncertainty in the assessment. Different weights are assigned to each impact category to reflect the importance of some impacts compared to others. Finally, policy options are compared on a pairwise basis and ranked through a FMCA, considering uncertainties in qualitative assessment and explicit weights assigned to impact categories. Our preliminary results show that, among the 5 policy options considered, the 'co-regulation' approach appears to be the preferable option.

**Keywords** Food safety regulations; Regulatory impact assessment; Multi-criteria analysis; Fuzzy logic; Dioxins

**JEL codes** D81; Q18

# 1. Introduction

All major regulatory proposals (in all policy areas, including food safety) need to be examined through a Regulatory Impact Assessment (RIA) before being approved and entering into force. This happens in the European Union (EU) as well as in many other countries throughout the world. A RIA consists of a series of steps involving an assessment of all likely economic, social and environmental impacts of various alternative policy options addressing the same problem, and a comparison of the options in order to obtain an indication of ‘the most preferred’ option.

RIA in the food safety policy area poses several challenges. To quantify the future effects on public health being produced by a policy initiative aiming at reducing risk for consumers from ingestion of contaminants in food is very difficult – if not impossible due to the number of interacting factors. Likely effects that need to be accounted for when considering different policy alternatives targeting at the same objective include the costs for businesses and public authorities, the distributive effects on different population groups and types of firms, the implications for international trade, etc. In addition, it is a fact that policy makers (need to) include societal concerns, especially in the aftermath of a food crisis, when taking a decision over the opportunity to implement a regulation or not. Options of removing food products from the market in the interest of food safety need to be balanced against food security and availability in places where food is short.

Recently, a food safety crisis pushed the EU to revise its own regulations, i.e. the contamination of animal feed with dioxins occurred in Germany in December 2010 – January 2011, where sales of poultry, pork and eggs from more than 4,700 farms were halted. Dioxins are toxic chemicals that may generate negative effects both on human health and the environment. Tighter limits came into force from 1 January 2012 (European Commission, 2011)

As the last changes in legislation have highlighted problems in the current management of dioxins, the opportunity to consider different policy initiatives have been considered and their impacts assessed. We used a multi-criteria decision tool developed within the EC-funded MoniQA Network of Excellence for the ex ante impact assessment of food safety regulations. This tool is based on the EC Impact Assessment Guidelines (EC-IAGs) (European Commission, 2009) as far as the identification of the impact categories relevant for food safety policies and the steps to be followed for the impact analysis and options comparison are concerned. It follows a fuzzy multi-criteria analysis (FMCA) approach, which allows impacts to be estimated in different ways, as opposed to cost-benefit analysis (CBA), which is the most common procedure employed in RIAs, but can only include monetary estimates of future impacts. Within the fuzzy approach of MCA (see e.g. Meyer and Roubens, 2005 and references therein), it is possible to accompany discrete qualitative impact evaluations with an indication of uncertainty.

Presenting the preliminary results from this regulatory impact assessment exercise is the aim of this work. It has to be noted that this application refers to a real situation, but should not be considered as recommendations for policy making due to lack of certainty in the detail of the information we used.

The paper is structured as follows. The second section describes the concepts and steps of the MCA tool. The sample application is illustrated in the third section. In Section 4 we present our conclusions.

## 2. Methodological approach

We developed a tool that, on the grounds of the indications and principles outlined in the Impact Assessment Guidelines of the EC (European Commission, 2009), presents features specifically addressing the main problems in the food safety policy area: (a) identification of 14 impact categories that are deemed relevant for food safety policies, and a breakdown into sub-impacts where needed; (b) explicit consideration of uncertainty in the qualitative assessment of these impacts; (c) inclusion of the principle of proportionate level of analysis to identify those impacts for which quantification (and possibly monetisation) is needed, feasible and affordable; and (d) the possibility of evaluating simultaneously qualitative and quantitative assessments.

Three steps can be identified. First of all, policy options[1] are assessed for each category of impact through a qualitative assessment. Then, quantitative estimations can be entered for any impact, where possible. To this purpose, a feasibility filter can be used that gives a suggestion on the opportunity to perform a quantitative assessment. Finally, policy options are compared through fuzzy multi-criteria analysis (FMCA) considering uncertainties in qualitative assessment and estimation error for quantitative evaluations in order to obtain a ranking of options.

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[1] Policy options need to be identified, including the 'do nothing' (or 'status quo') option, i.e. the option of leaving situation as it currently is. This does not necessarily mean there will be no change since the policy that is currently in place may be having an impact and resulting in changes.

In order to deal with the specificities of food safety policies, we selected and adapted the economic, social, and environmental impacts listed in the EC-IAGs (European Commission, 2009, pp. 32-37), as can be seen in Table 1, with a breakdown of impacts into sub-impacts where appropriate. The impact list was integrated with the inclusion of societal concerns (public opinion and media, consequences on vulnerable groups, etc.), so that a decision maker may incorporate such considerations in a transparent and rigorous way.

The first step requires to evaluate each of the 14 impacts for each policy option, based on a qualitative scale. This qualitative indicator is obtained indirectly by combining four components of an impact: the 'direction' of the policy impact (whether positive, neutral or negative), its 'severity' (a measure of intensity of the effect on those that are interested by the policy), its 'scale' (which proportion of the reference population would be actually exposed to the policy effects), and its 'likelihood' (the probability that the impact actually occurs).

The scoring procedure converts qualitative statements on the above four components into an ordinal variable ($x$) which ranges between 1 (strong negative impact) and 9 (strong positive impact), where 5 is neutrality.

Another ordinal variable ($u$) captures the level of uncertainty in the assessment, which may be due to lack of information, disagreement among experts, and the confidence that assessors place into their qualitative statements. This variable ranges between 1 (maximum uncertainty) and 5 (minimum uncertainty).

The final output of the scoring step is a qualitative impact matrix ($I$), where each row is an impact, $n$ is the number of policy options and for each policy option a numerical value for $x$ (the qualitative score) and a value for $u$ (uncertainty in the assessment) are recorded.

Once the preliminary qualitative assessment of the policy options for all 14 impacts is performed, a feasibility filter may be used in order to determine the opportunity of pursuing a quantitative assessment for any of the 14 impact categories.

As for the previous step, the filter is rigorously structured. First of all, the relevance of the impact ($x$) and the level of uncertainty ($u$) are taken into account, with the assumption that impacts that are closer to neutrality ($x$=5) and with less uncertainty ($u$=5) are less in need of quantification. As the impact assessment moves towards the extremes ($x$=1 or $x$=9), and/or uncertainty rises (a smaller $u$), then quantification becomes more important.

Beyond this, the filter follows the principle of proportionate level of analysis by considering (a) availability of primary and secondary data for impact quantification; (b) the costs for data collection and analysis relative to available resources; and (c) the presence of time constraints. Also based on the filter indication, the evaluator can make the ultimate choice about replacing qualitative (fuzzy) judgements with quantified (stochastic) impact evaluations within the impact matrix. When impact evaluations are quantitative, *x* will be replaced by the expected value of the impact variable for each policy option and the standard error of this estimate will be used as an uncertainty measure in place of *u*. Any measurement unit can be chosen, provided it does not change across policy options within the same category of impact .

The final step provides the ranking of policy options through fuzzy multi-criteria analysis. Among the many procedures available for running FMCA (Figueira et al., 2005), we heavily draw from the one proposed by Munda for environmental impact assessment named NAIADE (Munda et al., 1995).

The stages needed to produce a (fuzzy) ranking of policy options are the following:

1) Transform the qualitative variables into Gaussian fuzzy sets;
2) Compute distances between pairs of policy options for each individual impact category, based on fuzzy sets and/or stochastic variables;
3) Produce a pairwise comparison between policy options based on the above distances and the weight assigned to individual impact categories;
4) Rank the policies based on how they perform in pairwise comparisons between each other.

A fuzzy set is defined through a membership function for each of its elements. So, if the elements of a fuzzy set are the discrete (ordinal) values between 1 and 9 – as in the present case – a degree of membership is needed for each of these nine values .

Consider a fuzzy set $S^k$ where *k:* 1,…,9 are the potential values that $x_{ij}$ may assume, and the actual assessment is $x_{ij} = q$ , where *q* is a single value between 1 and 9. The membership function is defined as follows:

$$\mu_{S^k}(x_{ij} = q) = \exp\left(-\frac{(k - x_{ij})^2}{2\sigma_k^2}\right) \quad (1)$$

Where *k* is the centre of the fuzzy set $S^k$ and $\sigma_k$ is the width of the fuzzy set $S^k$ (i.e. a measure of dispersion around the centre). While in NAIADE the dispersion parameter $\sigma_k$ is fixed, here we allow dispersion to be a function of the centre $k$ of each fuzzy set and of the stated uncertainty level $u$. The assumption is that dispersion is larger for assessments around 5 (neutrality) and for smaller values of $u_{ij}$ (i.e. larger subjective uncertainty). Given that the standard deviation for a continuous uniform distribution[2] ranging from 1 to 9 is 2.58, we adopt this value as the maximum variability level. The equation for $\sigma_k$ is thus the following:

$$\sigma_k = \frac{(6 - u_{ij}) \cdot 0.2 + \min(k, 10 - k) \cdot 0.2}{2} \cdot \mathbf{2.58} = \left(6 - u_{ij} + \min(k, 10 - k)\right) \cdot \mathbf{0.258}$$

with $k$=1,…,9 (2)

The Gaussian membership functions return a value between 0 and 1, where $\mu_{S^k}(x_{ij} = q) = \mathbf{1}$ when $q$=$k$.

Once the impact matrix in equation (1) has been built and the membership values have been computed for qualitative variables according to equation (2), the ranking of policy options can be obtained through fuzzy multi-criteria analysis. The mathematics between this approach closely follows those by Munda et al. (1995).

First, pairwise distances between policy options need to be computed for each impact category. When the impact measurement is qualitative for a given impact category, the distance between the two fuzzy sets is the semantic distance described in Munda et al. (1992). Instead, for quantified (stochastic) impacts, we adopt the Hellinger distance between normally distributed variables. After rescaling of the respective equations (see Appendix C), these two types of distances are bound between 0 (minimum distance) and 1 (maximum distance), which makes them perfectly comparable. This ultimately allows for simultaneous consideration of qualitative and quantitative impacts and multiple measurement units.

These pairwise distances are the basis to assign credibility values to a set of 6 statements (preference relations) on the comparison between two policy impacts according to a given impact category, i.e. that one policy is much better (better, approximately equal, equal, worse, much worse) than the alternative, for a given criterion. This generates 6 credibility values for each of the 14 impacts and each pair of policy options. Credibility values range between 0 (no credibility at all) and 1 (maximum credibility) and are a function of the computed

[2] The conservative assumption of a continuous rather than discrete distribution is needed because qualitative scores for impacts may result as an aggregation of sub-impact scores, as described in Appendix A.

distance. This ‘credibility’ framework is consistent with the fuzzy logic and the presence of internal and external uncertainty on the expected outcomes of a food policy.

The next step is the aggregation of the pairwise comparison between two policy options across the 14 impact categories. Aggregation is pursued through a relatively straightforward average of the credibility indices for each pairwise comparison of policies, which enables the introduction of relative weights to discriminate across impact categories with different relevance. This is a key element of flexibility, which may reflect different stakeholder perspectives (e.g. the relative weight of health outcomes versus industry costs) and allows to check for robustness of the policy ranking in relation to different preference structures, by reproducing the analysis with different sets of weights.

After this first aggregation stage, a single preference intensity index is produced for each of the 6 statements and for each pair of policy options.

The final step of the fuzzy multi-criteria procedure consists in the final ranking of policy options. A measure of how the policy ranks compared to all alternatives is based again on an average of the preference intensity indices. At this stage, the six sentences on pairwise comparison are simplified into two key categories: the statement that a given policy is ‘the best option’ and the counter-statement that the same policy is ‘the worst’. As before, each statement needs to be associated with a membership value according to the fuzzy logic. The ‘best option’ and ‘worst option’ membership values are the 2 finale ranking indices.

These synthetic indices are based on the ‘performance’ of each policy option against all others, where the times the option is ‘much better’ or ‘better’ than the alternatives increase the best option index, and the occurrences of the ‘worse’ or ‘much worse’ preference intensity indices generate an increase of the worst option index.

One further step which may significantly improve the quantification of the 2 final indices is the explicit consideration of the degree of consistency across the 14 impact categories. This is the so-called ‘entropy’ weighting, which reflects the degree of inconsistency among criteria assessment values within a policy option.

# 3. Application

We present here an application on different regulatory interventions regarding the occurrence of dioxins and PCBs in food, in order to illustrates the main advantages of the proposed procedure.

Dioxins is the collective term used to refer to polychlorinated dibenzo-*p*-dioxins (PCDDs) and dibenzofurans (PCDFs), that arise as a result of combustion processes, as by-products in the manufacture of organochlorine compounds or as a result of activity of the chlorine industry. Although exposure could occur through inhalation of air, dermal absorption, consumption of drinking water and consumption of food, the last is the predominant route for the general population and accounts for over 90% of human exposure (Startin and Rose, 2003).

Polychlorinated biphenyls (PCBs) are a group of compounds that were manufactured until the 1980s for use in various ways, including electrical products (e.g. as a dielectric in transformer oil). They are also ubiquitous environmental pollutants, and it has also become widely accepted that some PCBs elicit dioxin-like biochemical and toxic responses. These are the co-planar PCBs, i.e. those with no or only one *ortho* substituent. Assessment of the health risks of exposure to dioxin-like chemicals must therefore consider these PCBs in addition to the dioxins.

Because of their toxicity, both dioxins and dioxin-like PCBs need to be measured at extremely low concentrations in food, and the sum of dioxins and dioxin-like PCBs present is usually expressed in picograms (1 pg = $10^{-12}$ g) of dioxins per gram of food (Van den Berg et al., 2006). In addition to the general environmental contamination from dioxins and PCBs, there have been specific isolated events that have resulted in the release of these compounds into the environment and subsequently to their incorporation into food within a localized area.

Although regulatory limits for dioxins in food have been set on an *ad hoc* basis by various authorities in the past, the European Union became the first body to set extensive and comprehensive limits for these compounds.

The most important feature of such toxic chemicals is that they may pose negative effects both to human health and the environment. The so called ‘Dioxin Strategy’ adopted by the EC consists of actions for reducing the presence of dioxins both in the environment and in food and animal feed. Our focus in this paper is on actions in feed and food.

These EU regulations came into force in July 2002, and include limits for PCDDs/PCDFs in food and animal feed (European Commission, 2006). Limits for dioxin-like PCBs were subsequently included. The regulation was supported by a monitoring plan, and by strict performance criteria for analytical methods that are used. Following a review in 2005 by the WHO on the relative toxicities of the individual dioxin and PCB congeners, and with the results of monitoring and surveillance efforts since the introduction of this legislation, the EU revised these limits taking effect from 2012 (European Commission, 2011). These new limits do not have an overall impact on the assessment reported in this paper.

In summary, dioxins are currently managed within the EU with a regulation on maximum levels in feed and food, a recommendation on action levels, and a legislation on analytical methodology and monitoring for feed and food.

As pollution control measures are introduced and come into effect, levels of dioxins and PCBs in meat have started to show a downward trend. The same is true, but to a lesser extent, for fish, possibly because the aquatic environment is the 'sink' for these chemicals, and because of their long half lives (Startin and Rose, 2003).

For the purposes of applying Scryer we considered 4 possible policy options against the *status quo*. We know that the population is currently exposed to levels of dioxins at or around the TDI, as a result of the ubiquitous nature of these compounds and underlying environmental contamination. We therefore decided to examine the impact of what might happen if limits were halved in order to give the public better protection with respect to exposure. Since we know that much of the food supply would be likely to exceed these proposed tighter limits, and that the existing limits already place a burden on industry, we decided also to compare this against de-regulation – the situation that in any case exists in most of the world outside Europe.

Dioxins analysis is expensive and there is limited capacity for enforcing limits that are in place. Even within the EU where there is harmonised regulation, there are very different approaches to enforcement by different Member States, with some countries undertaking much more control and monitoring than others. Therefore, in addition to looking at the impact on changing limits, we also examined the impact of stricter enforcement of the regulations that are already in existence. Here we opted to look at two different approaches, the first where the public authorities undertook a more extensive official control programme and conducted more tests and the second where there was an obligation in industry to undertake their own testing, with the public authorities providing an audit or check that this was being done – a co-regulation option.

### 3.1 Qualitative assessment

The evaluation matrix is shown in Table 2. The second column shows the relevance score we assigned to each category of impact. The third column transforms the relevance scores into weights ranging from 0 to 1. The remaining columns report the qualitative indicator X and the uncertainty level U for each policy option/impact combination.

We now provide a descriptive assessment of the policy options for each impact category, which guided the structured qualitative assessment performed with Scryer.

Impact on public health

The future impact of the *status quo* situation is considered as slightly negative to reflect the risk of lack of efficient and harmonised controls across EU countries, even though, if things will be left as they are, incidence of dioxins (and consequently risk for public health) could possibly decrease because of pollution controls that are already in place and not necessarily as a direct result of the current regulations on maximum levels in food and feed. Pollution controls are considered an external factor which is not included in this assessment.

Halving limits would have a large positive impact on chronic effects for human health, since exposure to dioxins will be reduced as a result of lower limits, assuming these are implemented. However, this option would certainly be too burdensome to comply with for the food industry, so a large quantity of food would not comply and have to be wasted, and this in the wider term could contribute to global food shortages. So health benefits arising from a lower content of dioxins in food would be counteracted by negative health effects in terms of under- and mal-nutrition as a result of less and/or unaffordable food. In order to take this indirect effects into account, we set a very high level of uncertainty to the assessment of halved limits. De-regulation would have a strong negative impact.

An effort for harmonising and improving official controls (policy option 4) is expected to greatly decrease the health risk for consumers; similarly the co-regulatory approach (option 5).

The level of uncertainty is moderate with some difficulty in predicting the effects on public health.

Impact on firm competition

Policy initiatives on dioxins are expected to not impact the market competition of the food sectors involved, as they would not alter the composition of firms in terms of number, size and market shares. In particular, they should not pose any risk of oligopoly or monopoly, which are considered as market failures for an effective competition in an open economy.

However, if we consider dioxin standards as a trade barrier, from the EU-firms perspective a restriction on imports has to be considered as a positive impact (options 2, 4 and 5). Moreover, placing safer food on the international market would presumably improve the global competitive position of EU firms with respect to firms operating in third countries. On the other side, de-regulation would worsen the current situation, as it would remove the reason for the competitive advantage of EU firms. The level of uncertainty is quite high, due to lack of adequate information (U = 2 across all regulatory options).

Impact on the conduct of businesses

From a food business point of view, regulations on dioxins – or the absence of any sort of regulation – imply not only costs for implementing requirements (e.g. sampling and analysis) but also the risk to be forced to withdraw batches of product already placed on the market or even to close down. In addition, there is the possibility of greater impacts for SMEs that would need to be accounted for.

Obviously, halving limits and tighter official controls would imply more compliance costs for affected firms than the current regulation, and co-regulation would even more imply more costs for businesses as a consequence of increased testing to be carried out on their own. On the other side, de-regulation will remove all existing compliance costs for businesses (the impact is positive).

Tighter controls and co-regulation are thought – with a high level of uncertainty – to produce a slight increase in costs or availability of essential inputs, like food products used as ingredients for other food products. With a regulation imposing stricter limits, many foods would not comply, including foods used as inputs for other food, so the impact of this option would be very negative. De-regulation will have no effects, as with the existing regulation prices of inputs have not increased.

If the current regulation will continue to be implemented as now, there could be some probability – even if small – that a new incident occurs and some batches of food are recalled. In case of a regulation halving current limits, the impact would be even more negative as more cases of firms not complying with a stricter regulation would certainly arise. On the other side, more efficient controls – either public (option 4) or both private and public (option 5) – may significantly decrease the probability of products withdrawn from the market (quite large positive impact). Firms would also benefit from de-regulation as food batches cannot be found to exceed legal limits[3].

There are particular businesses that could be more affected by regulations and controls on dioxins, like fish and some meat industries. Only a de-regulatory option would remove stricter requirements for such firms, whilst regulatory requirements would become more

[3] It could be argued that a problem on dioxins could arise even in absence of a regulation, but it would be less emphasised especially if we consider that maximum limits for dioxins in food do not exist elsewhere outside EU. In addition, here we opted for a positive impact in order to highlight the difference with the status quo option.

stringent than the current regulation as we opt from co-regulation, to tighter public controls and to halved standards.

If we leave things as they are (do nothing option), some businesses could close down because of a dioxin incident, with the same pattern as it has happened in the past (neutral impact). This possibility would heavily worsen in case of a stricter regulation since there would be much more infringements of the limits. With better and tighter controls (options 4 and 5), the risk of an incident would decrease and consequently so would the probability of a business being forced to close down. For a different reason (absence of legal maximum limits), de-regulation will presumably have a positive effect in this respect.

Impacts for very small enterprises (the majority of EU agricultural and food businesses) would be more severe – compared to larger firms – for all alternative regulatory options (especially in case of halved limits) than the *status quo* situation. On the other side, SMEs will benefit even more from compliance cost removal with de-regulation.

Overall, the 3 regulatory scenarios (halving limits, tightening controls, co-regulating) we compare to the *status quo* imply more costs for businesses, with the most severe effects in case of halved limits, then in case of tighter official controls , and finally co-regulation. Leaving things as they currently are (*status quo* option) would imply slightly negative impacts on businesses, mainly due to a possibility of withdrawals of food already placed on the market as consequence of poor official controls before product commercialisation. De-regulation would write any compliance cost off (large positive impact). The uncertainty in assessment is around the intermediate level.

Administrative burdens on businesses

Intuitively, costs for businesses to meet legal obligations to disclose information on their compliance with the regulation would be greater in case of stricter standards and tighter official controls than the current regulation. De-regulating dioxins in food would eliminate the actual burdens to industry (positive impact), and co-regulation is expected to have a neutral impact in comparison to current regulation, as a result of decreased legal obligations to be met (self-regulation implies less administrative burden than regulation imposed by government), and increased burdens as a result of more controls[4].

Public authorities

[4] http://ec.europa.eu/dgs/secretariat_general/simplification/simpl_meth/simpl_meth_en.htm Accessed on 26 March 2012.

Costs for implementing the policy and performing official controls and administrative burdens[5] borne by public authorities will increase with stricter limits and tighter official controls, compared to the *status quo* situation. In case of co-regulation, costs for public authorities will not be as high as halving limits and tighter official controls, as they will be confined to auditing expenses to ensure compliance. In case of de-regulation, costs for public authorities would still be higher due to costs to face probable dioxins incidents and to perform routine official analysis on dioxin occurrence in food, but the administrative burdens would be cancelled (the resulting neutrality of the overall impact of de-regulation results as an average of the 2 sub-impacts).

<u>Innovation and research</u>

A regulation on dioxins should theoretically stimulate research and innovation, specifically in terms of elaborating more accurate sampling strategies and analytical methods. With the current regulatory setting cheaper and faster tests will presumably be sought and produced in the future. Stricter standards will push into developing more precise methods capable of detecting smaller amounts of dioxins in food. With a higher degree of uncertainty, we think that – to a less extent than stricter standards and more than the *status quo* – more rigorous controls and co-regulation would also stimulate innovation in sampling and analytical methods. On the other side, de-regulation will provide no incentive to introduce more improvements to the existing technology in the future .

In terms of productivity/resource efficiency, the value added per unit of resource input will probably increase in case of stricter standards, tighter public and private/public controls (options in increasing order), if we consider that products could be sold as having a higher quality, but would decrease in case of de-regulating.

<u>Impact on consumers</u>

A policy on dioxins could have non-health effects on consumers mainly in terms of food product prices, as dioxins do not change organoleptic characteristics of food (like taste or smell), and as the regulation may affect most categories of food it wouldn't affect consumer choices or preferences.

As industry would probably bear the costs of tighter official controls without passing them onto consumers, we set impact of this option on consumer prices as neutral, whilst a co-regulatory approach, with a very active involvement of the industry sector in performing analyses, would presumably imply slightly higher retail food prices. Halving limits would

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[5] Administrative burdens for public authorities are intended as additional administrative costs for collecting and storing information provided by businesses as required by the regulation.

cause tremendous costs for food industry as a large quantity of food would not comply, so these costs and food shortages would results in higher retail prices of concerned foods. The status quo situation and de-regulation would obviously have no consequences in terms of food prices.

Impact on international trade

Sub-impacts on countries with which the EU has preferential trade agreement, on international obligations like for the WTO (as EU is already the most regulated region in the world, and increased regulation is unlikely to make a difference), on foreign businesses operating within the EU borders (assuming regulation applies equally to foreign and internal businesses) are not considered as relevant for dioxins in food products. In general, food policies on dioxins would not have any effect on trade flows between EU and third countries, as third countries are already aware of more controls on dioxins within EU.

There would also not be any adjustment cost for developing countries with all policy options.

Overall, there wouldn't be any impact of any policy option on international trade, although the degree of assessment uncertainty is quite high.

Impact on the macroeconomic environment

As for international trade, with a quite low level of uncertainty any policy option wouldn't affect macroeconomic variables like GDP, inflation rate, etc., because of the relatively low importance of such a type of issue (a type of contaminant in selected food categories) with respect to the overall economy of countries.

Impact on labour markets

With a higher uncertainty than for the impact on macroeconomic environment, we expect no impact of the policy options on the labour markets in terms of jobs losses or creation, as the increase in personnel demand for enforcing the regulation in terms of increased controls, increased sampling and analyses is expected to be negligible and would then be absorbed by the existing personnel in public authorities and firms.

Impact on the environment

This impact category is very interesting in the case of dioxins, as they are environmental pollutants, so regulations in food can have a stake in the background level of dioxins in the environment. Effectively, the only way to reduce the background levels in food (as opposed to incidents) is to reduce the levels in the environment. Consequently, stricter standards, tighter official and co-regulatory controls could result in concurrent stricter environmental regulation that would have positive effects on the environment, whilst de-regulating will go in the opposite direction. However, the uncertainty of the assessment is quite high, due to knowledge gaps.

Distributive effects

As far as consumers are concerned, infants, young children, pregnant women, and high consumers of fish (included in the group category 'minorities') would be especially protected by stricter limits and tighter official, and co-regulatory controls, whilst de-regulation would have negative effects. Such population categories would also be slightly negatively affected if we leave things as they are (status quo option), as a consequence of poor controls and lack of harmonisation in implementation among EU member states.

Very small businesses and firms operating in vulnerable sectors (like those of fish oils, oily fish, and some meat products) would face a higher regulatory burden than the other businesses with halved maximum limits (option 2) and tighter controls (options 4 and 5). There could be also negative effects for vulnerable regions, like the Baltic Sea area, whose agri-food economy is based on fish. Especially in case of halving limits, such vulnerable categories of businesses would face a much higher risk of not complying with legislation. On other side, de-regulation would remove any burden for these particular businesses, sectors and regions.

Societal concerns

The majority of laypeople are unaware of the health risks associated with dioxins in food, but some sectors of the population are very concerned. Media coverage on the issue has usually abounded at the circumscribed period of dioxins incidents. Consequently, we considered the impact of all policy options on societal concerns as neutral, with a fairly low degree of uncertainty.

### 3.2 Comparison of policy options

Once the qualitative assessment has been performed, and the evaluation matrix has been produced through the scoring procedure, the fuzzy multi-criteria comparison of policy options is run in Eviews. The final output, i.e. the 'best option' and 'worst option' indexes for each policy option, is shown in Table 3, which consists of 4 boxes. Each box (named 'not weighted', 'entropy', 'explicit weights', and 'explicit weights and entropy', respectively) displays results depending on the inclusion or not of the explicit weights (second column of Table 2) and/or the entropy weights.

The only results which are homogeneous across the 4 boxes are that:

- co-regulation has the highest ‘best option’ index (with a large distance from the second-best option),
- co-regulation has the lowest ‘worst option’ index (with a large distance from the second-worst option), and
- the ‘status quo’ option has the lowest ‘best option’ index.

For the rest, results are quite homogeneous (in absolute index values and in policy ranking) in the first two boxes (‘not weighted’ and ‘entropy’), and in the last two boxes ( ‘explicit weights’ and ‘explicit weights and entropy’), i.e. depending on consideration or not of explicit weights. This immediately highlights the importance of assigning explicit weights to the final output of Scryer. In this case, public health was given a very high weight compared to the other impact categories.

If calculations are made without considering the explicit weights given to the impacts (‘not weighted’ and ‘entropy’ boxes of Table 3), de-regulation ranks as the second-best option, but also has the highest worst options index, meaning that it could probably turn out to be the wrong choice. Improving official controls (option 4) is ranked as third in the best option index, and has the second lowest worst option index. The fourth best option is the stricter standard (option 2), which is also the third worst option. The status quo is the second worst option.

When we consider the explicit weights (‘explicit weights’ and ‘explicit weights and entropy’ boxes), rankings for the best-option and worst-option indexes are specular:

- Best option: co-reg > controls > halving > de-reg > status quo
- Worst option: status quo > de-reg > halving > controls >co-reg

Overall, co-regulation seems by far  the preferable option to pursue, and leaving the current regulation has the highest probability to reveal as the worst future scenario.

# 4. Conclusion

This paper shows a the preliminary results of a regulatory impact assessment exercise on alternative policy options to tackle the presence of dioxins and PCBs in food. The employed method accounts for subjectivity and uncertainty at the same time and is made transparent thanks to its rigorous structure. These seemingly conflicting characteristics can be achieved by combining an explicit scoring system with indicators of uncertainty in assessments, and through the application of fuzzy logic to multi-criteria analysis.

This application shows the peculiarity of tool in aggregating different impacts without the need for monetisation, and the possibility to test for the robustness of the evaluation outcome by changing the relative weights of different impact categories.

Finally, this work shows a procedure that takes into account a key principle of impact assessment: the proportionate level of analysis. By considering the existence of time and budgetary constraints faced by the assessor(s), it allows for a rapid qualitative assessment (as in this case, where only qualitative assessment is performed) as well as the inclusion of more expensive and complex estimates on individual impacts, the tool can be adapted to a variety of needs.

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Table 1 - List of potential impacts (with possible sub-impacts) of food safety regulations

| |
|---|
| **1. Public health** |
| 1.1 - Acute effects on human health |
| 1.2 - Chronic effects/post-infectious acute effects on human health |
| **2. Firm competition** |
| 2.1 - Creation of barriers for new suppliers and service providers |
| 2.2 - Facilitation of anti-competitive behaviour or emergence of monopolies |
| 2.3 - Market segmentation |
| 2.4 - Global competitive position of EU firms |
| 2.5 - Trade barriers |
| **3. Conduct of businesses/SMEs** |
| 3.1 - Additional adjustment, compliance, transaction costs |
| 3.2 - Cost or availability of essential inputs |
| 3.3 - Access to finance |
| 3.4 - Investment cycle |
| 3.5 - Stricter regulation of the conduct of a particular business |
| 3.6 - New or closing down of businesses |
| 3.7 - Products or businesses treated differently |
| 3.8 - Impact on SMEs |
| **4. Administrative burdens on businesses** |
| **5. Public authorities** |
| 5.1 - Budgetary consequences |
| 5.2 - Administrative burden |
| **6. Innovation and research** |
| 6.1 - Academic or industrial/public or private R&D |
| 6.2 - Introduction and dissemination of new production methods, technologies and products |
| 6.3 - Productivity/resource efficiency |
| **7. Consumers** |
| 7.1 – Prices |
| 7.2 - Organoleptic characteristics (taste, smell, sight, touch) |
| 7.3 - Consumer choice |
| 7.4 - Consumer preferences |
| 7.5 - Provision of affiliated public goods (i.e. ethical value) |
| **8. International trade and third countries** |
| 8.1 - Trade or investment flows between the EU and third countries |
| 8.2 - EU trade policy and its international obligations, including in the WTO |
| 8.3 - Specific groups (foreign food businesses and consumers) |
| 8.4 - Third countries with which the EU has preferential trade arrangements |
| 8.5 - Adjustment costs on developing countries |
| 8.6 - Goods or services that are produced or consumed by developing countries |
| **9. Macroeconomic environment** |
| 9.1 - Economic growth |
| 9.2 - Conditions for investment and the proper functioning of markets |
| **10. Labour markets** |
| 10.1 - New job creation/loss of jobs |
| 10.2 - Particular professions, groups of workers, or self-employed persons |
| **11. Environment** |
| **12 & 13. Positive and negative distributional effects** |
| **14. Societal concerns** |

Table 2 - Evaluation matrix with qualitative assessment, uncertainty and impact weights

| *Category of impact* | *Impact relevance* | *Explicit weight* | *Policy option 1* *Status quo* | | *Policy option 2* *Halving limits* | | *Policy option 3* *De-regulation* | | *Policy option 4* *Tighter controls* | | *Policy option 5* *Co-regulation* | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | *X* | *U* | *X* | *U* | *X* | *U* | *X* | *U* | *X* | *U* |
| *Public health* | 10 | 0.34 | 3.00 | 3.00 | 9.00 | 2.00 | 2.00 | 3.00 | 9.00 | 3.00 | 9.00 | 3.00 |
| *Firm competition* | 1 | 0.03 | 5.00 | 2.00 | 7.00 | 2.00 | 2.50 | 2.00 | 7.00 | 2.00 | 7.00 | 2.00 |
| *Conduct of businesses/SMEs* | 3 | 0.10 | 4.78 | 3.33 | 1.44 | 3.00 | 7.67 | 2.78 | 3.67 | 3.44 | 3.78 | 3.44 |
| *Administrative burdens on businesses* | 2 | 0.07 | 5.00 | 5.00 | 1.00 | 4.00 | 9.00 | 4.00 | 1.00 | 4.00 | 5.00 | 4.00 |
| *Public authorities* | 2 | 0.07 | 5.00 | 4.50 | 1.00 | 4.00 | 5.00 | 4.00 | 1.00 | 4.00 | 5.00 | 4.00 |
| *Innovation and research* | 1 | 0.03 | 5.67 | 2.67 | 8.00 | 2.67 | 3.67 | 2.67 | 8.00 | 2.00 | 8.00 | 2.00 |
| *Consumers* | 1 | 0.03 | 5.00 | 5.00 | 5.00 | 2.00 | 5.00 | 5.00 | 5.00 | 3.00 | 3.00 | 2.00 |
| *International trade* | 1 | 0.03 | 5.00 | 3.50 | 5.00 | 2.50 | 5.00 | 2.50 | 5.00 | 2.50 | 5.00 | 2.50 |
| *Macroeconomic environment* | 1 | 0.03 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 |
| *Labour markets* | 1 | 0.03 | 5.00 | 3.00 | 5.00 | 3.00 | 5.00 | 3.00 | 5.00 | 3.00 | 5.00 | 3.00 |
| *Environment* | 1 | 0.03 | 5.00 | 3.00 | 6.00 | 2.00 | 3.00 | 3.00 | 8.00 | 2.00 | 8.00 | 2.00 |
| *Distributive effects - negative* | 2 | 0.07 | 3.33 | 3.00 | 1.67 | 3.00 | 2.00 | 3.00 | 3.33 | 3.00 | 3.67 | 3.00 |
| *Distributive effects - positive* | 2 | 0.07 | 5.00 | 3.00 | 7.67 | 3.00 | 6.00 | 3.00 | 7.67 | 3.00 | 7.67 | 3.00 |
| *Societal concerns* | 1 | 0.03 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 | 5.00 | 4.00 |

Table 3 - Final output from fuzzy multi-criteria comparison of policy options

| *Type of output* | *Options* | *Best option index* | *Worst option index* |
|---|---|---|---|
| *Not weighted* | *Status quo* | 0.12 | 0.26 |
| | *Halving* | 0.16 | 0.25 |
| | *De-reg* | 0.25 | 0.35 |
| | *Controls* | 0.19 | 0.21 |
| | *Co-reg* | 0.37 | 0.03 |
| *Entropy* | *Status quo* | 0.11 | 0.25 |
| | *Halving* | 0.14 | 0.24 |
| | *De-reg* | 0.24 | 0.34 |
| | *Controls* | 0.17 | 0.20 |
| | *Co-reg* | 0.37 | 0.03 |
| *Explicit weights* | *Status quo* | 0.12 | 0.53 |
| | *Halving* | 0.33 | 0.27 |
| | *De-reg* | 0.27 | 0.53 |
| | *Controls* | 0.34 | 0.21 |
| | *Co-reg* | 0.51 | 0.03 |
| *Explicit weights and Entropy* | *Status quo* | 0.11 | 0.51 |
| | *Halving* | 0.29 | 0.26 |
| | *De-reg* | 0.27 | 0.51 |
| | *Controls* | 0.30 | 0.20 |
| | *Co-reg* | 0.49 | 0.03 |