Briefing

Initial Appraisal of a European Commission Impact Assessment

European Parliament

July 2016

New rules on CE marked fertilising products

Impact Assessment (SWD (2016) 64, SWD (2016) 65 (summary)) of a Commission proposal for a regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (COM (2016) 157)

Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's Impact Assessment (IA) accompanying the above proposal, adopted on 17 March 2016 and referred to Parliament's Committee on the Internal Market and Consumer Protection on 11 April 2016.

Despite the wide use of fertilising products in European agriculture, the internal market for them is only partially harmonised. The existing Regulation No 2003/2003, which aims to ensure a free internal market in products labelled as 'EC fertilisers', covers about 50 % of such products on the market in the EU. Other fertilisers meeting national requirements (called 'national fertilisers') can circulate on the EU market under the 2008 Mutual Recognition Regulation. However, as Regulation No 2003/2003 covers only inorganic fertilisers, access to the internal market for almost all organic fertilisers (for example, produced from bio-waste), depends on mutual recognition by Member States. This situation hampers innovation (for more information, see the related EPRS briefing[1], and the Explanatory Memorandum of the proposal, p.3).

The new legislative proposal would repeal the 2003 Regulation. It is regarded by the Commission as an important step towards implementing the Commission's Circular Economy Action Plan as it facilitates access to and circulation of organic fertilisers in the common market. The proposal focuses specifically on three key aspects. Firstly, it aims to incentivise large scale production of organic fertilisers in the EU by creating a regulatory framework granting such fertilisers access to the internal market. Secondly, the proposal aims to stimulate innovation in this industry. Thirdly, it tackles the problem of health and environmental harm resulting from excessive levels of some fertilising products, such as cadmium, by setting harmonised levels for cadmium content in fertilisers across the EU.

In addition to the main impact assessment, which is the subject of this appraisal, the proposal is also accompanied by a second assessment on the specific issue of cadmium levels. This is referred to, in the text of this appraisal, as IA Part 2. The policy options of IA Part 2 are summarised in an annex to this appraisal for information.

Problem definition

The IA report identifies two main general problems namely: the lack of awareness about nutrient recycling, and the lack of an internal market for fertilising products derived from recycling of bio-waste and biomass (IA, p. 13-14). In addition to these problems, the IA report mentions more specific problems stemming from the weakness

[1] Bourguignon Didier, CE marked fertilising products. Briefing, European Parliamentary Research Service

Author: Vadim Kononenko
Ex-Ante Impact Assessment Unit
PE 581.417

of the legislation currently in place: e.g. lack of trust in mutual recognition instruments by economic operators, lack of consideration for environmental and public health concerns, divergences in environmental and human health safety standards (including cadmium content in phosphate fertilisers) between Member States, and market access problems for new products (IA, p.17, IA Part 2, p.25).

When defining the problem, the IA constructs and presents well the causal link between the drivers and the consequences. Conceptually, the IA report explains how a limited number of drivers, e.g. regulatory complexity and barriers to new and more sustainable products, lead to problematic consequences in the absence of an internal market for fertilising products (IA, p.24). As the IA states clearly, 'if no action is taken, legal and administrative divergences between Member States will increase leading to a more fragmented internal market for fertilising products' (IA, p.25).

Objectives of the legislative proposal

According to the IA report, the *general* objectives of the proposal are, firstly, to incentivise large-scale production of fertilisers from domestic organic or secondary raw materials by creating a regulatory framework granting such fertilisers access to the internal market, and secondly, to address the issue of soil contamination, by introducing harmonised cadmium limits for phosphate fertilisers (See Explanatory Memorandum p.4, IA Part 2, pp. 27-28). This objective stems from concerns that excessive levels of cadmium may cause harm to human health and the environment (in the form of contamination of soil and water). Some Member States currently have their own national limits on cadmium content in fertilisers, but there is no harmonised EU-wide approach.

There are four *specific* objectives, namely: to ensure an improved functioning of the internal market and a level playing field for manufacturers and importers of fertilising products; to reduce the administrative burden resulting from diverging national rules and incomplete application of the mutual recognition of fertilising products; to improve the safety of fertilising products as regards the protection of the environment and human health; to ensure coherence with other existing EU legislation in order to support investments in new economic opportunities for public and private operators. Most of the five *operational* objectives mentioned (to remove trade barriers; to limit pollutants levels; to reduce administrative burdens; to facilitate innovation; to streamline the information obligation requirements - see IA, p.27) do not seem sufficiently specific to correspond to the definitions provided in the Commission's 'Better Regulation guidelines' (see also the Monitoring and Evaluation section of this appraisal).

Range of options considered

Three options were discarded at an early stage, namely: improvement of mutual recognition without harmonisation; voluntary agreement by industry; and withdrawal of the EU legislation on fertilisers and reliance instead on other relevant existing legislations to ensure the safety of fertilising products (IA, pp. 29-30). The IA explains that the majority of stakeholders did not support these options which, indeed, given the magnitude and nature of the problems described, do not appear viable.

The IA report examined five policy options[2] (see below). It can be inferred from reading the IA that Option 5 is the preferred option (see the comparison table, IA, p. 66), although this is not explicitly stated in the report.

The five options are presented and examined in two variants: full harmonisation and optional harmonisation. The difference between the two is the scope of harmonisation. In the case of full harmonisation, the scope would be extended to all fertilising products (including 'national' fertilisers) on the EU market. In the case of optional harmonisation, the scope of harmonisation would remain as it is under the current regulation: producers who do not wish to have access to the whole EU market can choose to comply with national rules instead.

[2] For the options presented in IA Part 2 on cadmium levels, please see the annex to this appraisal

Option 1: The current EU legislation governing the placing on the market of fertilisers remains unchanged (baseline scenario).

Under the baseline scenario, the existing regulation would continue to apply to inorganic fertilisers. National laws and the mutual recognition would likewise continue to apply as they do at present. Also, no maximum limits for heavy metals in inorganic fertilisers (for example cadmium) would be adopted at EU level.

Option 2: creation of an internal market for fertilising products in the format of the current regulation, i.e. listing individual product types.

Under this option, the scope of the current regulation would be extended to cover several types of organic fertilisers. Maximum limit values for contaminants for each product category would be defined. Specific quality criteria would apply to each product category. Labelling requirements would apply to each product category in accordance with specific characteristics. The information on the labels would not only inform the users about the characteristics of the product but also aim to increase awareness about environmental aspects of a product.

Safety criteria limit values for contaminants would be proposed with values selected on the basis of stakeholder consultation after peer-review of available studies.

The IA report indicates that in case of full harmonisation, the producers and importers of fertilisers would have to wait up to 10 or 15 years to get their products registered in the EU list of authorised products.

Option 3: Creation of an internal market for fertilising products by listing authorised ingredients.

As compared to Option 2, which envisages the list of authorised product types, Option 3 prescribes that ingredients allowed in fertilising products would be listed in the annexes to a new regulation. Minimum quality criteria, as well as labelling requirements, would apply to each product category (IA p.32). The IA report does not specify how long it would take for producers and importers to register their products in the EU list, but it states that the waiting period would be shorter because the number of ingredients would be fewer than the number of product types (IA p.32).

Option 4. Creation of an internal market for fertilising products using the 'new legislative framework'.

According to the IA report, by using the 'new legislative framework' (NLF) for circulation of fertilising products, the process of making a product available on the market would become less prescriptive as the NFL restricts the content of legislation to 'essential requirements' and leaves technical details to other frameworks. Legal requirements with regard to safety (including the same limit values for contaminants as would be proposed under options 2 and 3), product quality and other specific rules appropriate for the placing on the market of safe and efficient fertilising products, would be specified for each product category (IA p.32). Unlike in Options 2 and 3, there would be no listing of ingredients or types and hence no need for frequent adaptation to technical developments. Producers or, alternatively, notified bodies designated by Member States, would have to declare conformity with the legal requirements. Option 4 includes three variants (4A, 4B, and 4C) which range from self-certification to various levels of third party certification (for a full description of the variants, see IA pp 32-33 and Table 47 in Annex III).

The IA report notes that the transitional period is relatively short (no specific timeline given) under Option 4, with the shortest waiting period being under the variant 4A, self-certification.

Option 5. Creation of an internal market for fertilising products and additives by adopting different variants of Option 4 for different types of fertilising products.

Option 5 follows from the previous option as it is based on the NLF as the main legislative framework. It envisages the regulatory regime for different kinds of fertilisers as a mix of the variants prescribed under Option 4. For example, most inorganic fertilisers would be regulated under variant 4A (self-certification), while a limited number of inorganic fertilisers would be regulated under variant 4B (third party certification), and yet other types of such fertilisers would be regulated under variant 4C (third party certification with additional tests on specific aspects). The IA report notes that 'the coexistence of three different certification procedures for inorganic fertilisers is feasible as the different product types are easily identifiable by market surveillance authorities' (IA, p.33).

All five options are directly linked to the problems and objectives presented in the IA. As Option 5 derives directly from Option 4 (being merely a combination of the variants of Option 4), the presentation would have benefited from a better explanation as to why option 5 could not have been considered as an additional variant of Option 4. By the same token, Option 2 and 3 seem to be two variants of one option. As the baseline option obviously does not lead to significant improvement of the problem, and considering that three options were discarded, the range of viable options is in fact limited to two choices - full or optional harmonisation - and which variants (sub-options) to include in the final mix.

Scope of the Impact Assessment

The IA assesses all five options for their economic, social, and environmental impacts. The IA assessed each impact with the help of specially defined criteria while also providing information on how these criteria are linked to the policy objectives (IA, p.35 and Annex VIII). There is a mix of one quantitative and eight qualitative criteria, all comprehensive and relevant for the assessment of the impacts.

As prescribed by the Better Regulation guidelines, the options are compared taking into account effectiveness, efficiency and coherence. The IA uses a scoring method for comparing the options, ranging from strongly negative to strongly positive as compared to the baseline scenario. The chart gives a very clear indication in favour of Option 5; however, this is not stated explicitly in the text of the IA report. As it is merely a combination of variants under Option 4, the impacts of these two options are similar.

As far as *economic impacts* are concerned, both Options 4 and 5 would lead to improvement in the functioning of the market by simplifying procedures for product categories (IA, p. 56). In a similar vein, NLF procedures are expected to deliver a reduction in administrative, compliance and market surveillance costs. Both these options would also support competitiveness and innovation capacity, particularly for the organic fertilisers sector.

With regard to *social impacts* both Options 4 and 5 would support job creation. The IA report cites a possibility of creating 66 000 'non de-localisable' jobs in the specific sector of industry related to recovery of phosphorus from biomass, but it does not provide further information or any further examples of where, and what, new jobs could be created.

As for *environmental impacts*, the IA report focuses on the reduction of greenhouse gas (GHG) emissions generated during the production of biomass derived fertilising products. Option 5 is stated to contribute positively to improved air quality by providing the necessary information to farmers about the potential release of ammonia from the fertilisers they use (IA, p.60).

In general, the IA explicitly places the focus on those economic impacts where the positive impacts are easily apparent in terms of reduction of red tape and better circulation of fertilising products. The analysis of impacts would have definitely been more plausible if more concrete examples had been given with regard to social and, especially, environmental impacts.

Subsidiarity / proportionality

The legal basis for the proposal is Article 114 of the TFEU which is also the legal basis for the existing fertilisers' regulation. The IA presents a rather clear, albeit somewhat circular, argument to justify an EU-wide approach. It points out that the problems caused by the weaknesses of the current regulation 'cannot be resolved by Member States alone as a revision of the regulation requires an EU action' (IA p.25). According to the Explanatory Memorandum, the existing barriers to the free movement of 'effective, safe, innovative' fertilising products produced from organic or secondary raw materials cannot be removed through unilateral actions of Member States (Explanatory Memorandum, p.6). Also, 'EU-wide maximum limits for cadmium content in fertilisers can effectively reduce contaminants in harmonised fertilisers' (Explanatory Memorandum, p.6, IA Part 2, p.24). According to the IA report, establishing maximum levels in the product legislation is seen as the means of addressing the problem 'at source'. This too cannot be done by Member States alone.

With regard to proportionality, the form of a regulation is deemed the most appropriate for the harmonisation of products in the field of fertilisers. The Explanatory Memorandum cites 'technical complexity and potential impact on the food chain and the environment' (Explanatory Memorandum p.7) as justification for the choice of legislative instrument. Although the IA report does mention that the issue of proportionality will be discussed at more length in various chapters, it does not dwell on it particularly, and does not appear to include an explicit analysis of the compliance of the options with the proportionality principle, contrary to what is required by the Better Regulation guidelines.

No reasoned opinions were submitted by national parliaments.

Budgetary or public finance implications

It is indicated that the proposal will have no negative implications on the EU budget (Explanatory Memorandum, p. 9). According to the IA, the costs related to EU governance and national administration seem to decrease under all the options and disappear altogether under the full harmonisation variant of Options 4 and 5.

SME test / Competitiveness

As far as the analysis pertaining to SMEs is concerned, the IA uses its own estimates based on the information collected 'from various industry federations'. The IA cites a lack of relevant Eurostat statistics as the explanation. According to the IA, under the NLF (which is the basis for both Options 4 and 5), SMEs are likely to benefit from improved business opportunities, easier innovation and greater competition, in particular for inorganic fertilising products (IA, p.64). The IA report also provides results of an SMEs and Competitiveness Proofing Test in Annex IV (IA, p.153). The test involved SMEs from ten Member States representing 2 % of the SMEs active in the relevant sectors of industry. Despite this low representation, the test survey is rather comprehensive in terms of the range of questions and it gives a good overall presentation of viewpoints of the SMEs concerned. However, the presentation and value of the survey (which seems to be based on a 2011 externally commissioned study) would have benefited from being more aligned with the text of the present IA report. For example, it is difficult to understand in what way the seven options that were given to the participants of the test correspond to the five options presented in the IA report. Yet, the SMEs test concludes with certainty that the majority of the respondents are not satisfied with the baseline scenario and welcome a revision of the current regulation.

Simplification and other regulatory implications

The proposal is intended to lead to the simplification of the administrative burden for producers of fertilising products since access to various national territories within the single market would not depend on mutual recognition. As the IA states, the variant of the optional harmonisation of Option 5 (the option that the proposal follows to the fullest) 'would have the advantage of affecting only economic operators with a genuine interest in getting access to the market in several Member States, in line with the principles of subsidiarity and better regulation' (IA p.57).

In addition, the use of NLF is meant to simplify several regulatory and governance processes, for example, there would be fewer meetings of competent authorities such as the Regulatory Committee (IA, p. 57).

Relations with third countries

The achievement of the objectives of the proposal would undoubtedly affect third countries as exporters of fertilisers to the European market. Given the EU's high dependence on import of phosphate rock, one of the main fertiliser components from third countries (Morocco, Tunisia and Russia), and the assumption that, in a more circular economy (which the current proposal aims to implement), 20 to 30 % of the EU's demand for phosphate

fertilisers can be covered by domestic sources (Explanatory Memorandum, p.3), it is logical to assume that the proposed regulation would be likely to have significant effects on the EU's relations with phosphate exporting third countries.

Nevertheless, the IA report does not include a separate analysis of impact on third countries. Instead, these aspects are analysed as part of the economic impacts assessment, alongside impacts on competitiveness and innovation. It is interesting to note that the impacts on international trade remain similar within the entire range of options, manifesting themselves in longer delays for producers and importers to obtain authorisation for all the types of fertilisers that would be covered by the new regulation (IA, p.41). In this regard, IA part 2 fills the gap, if only partially and only regarding cadmium, by providing an analysis of how the imposition of limits on cadmium content would affect the EU's imports of phosphate fertilisers from Morocco (IA Part 2, p. 43). Some useful background information in this respect can be found in Annex I (IA, p.73).

Quality of data, research and analysis

The IA report brings together and makes use of several pieces of analysis. The study to which numerous references are made in the IA report is the ex-post evaluation study of the existing regulation conducted in 2010[3]. This serves as the analytical base for the entire IA report. Another piece of research used for the IA report is an external consultant's study requested by the Commission in 2011.[4] The IA report significantly develops the findings of the 2011 study by discarding some of the options and reworking others.

The IA report relies mostly on qualitative data (e.g. review of discrepancies in national legislative frameworks) with only limited use of statistics. The Commission explains that this is due to the difficulty in obtaining reliable EU-wide statistics. Especially when it comes to the data used in the IA Part 2, the analysis frequently cites the lack of available data and chooses to speak in terms of high or low probability. A broad range of background studies on human health were also used (for example UNEP Final Review, 2011). These studies are used to illustrate various potentially harmful effects of different contents of fertilising products (for example, cadmium, Annexes V and VI, IA Part 2, pp. 58-63).

Stakeholder consultation

The IA clearly identifies the stakeholders affected by the problem to be solved and the proposed regulatory solutions (IA p. 22). They include European SMEs involved in manufacturing fertilisers, public and private operators in the waste treatment sector, national authorities and other groups (IA p.23). The Commission appears to have consulted stakeholders extensively via different channels (e.g. ad hoc working groups organised in preparation of the proposal and co-chaired by a representative of the Commission and a Member State expert; a public consultation on the Circular Economy), but does not appear to have conducted the mandatory twelve week open public consultation for the preparation of the IA. The opinions of Member States appear to be given more importance than those of other stakeholders (industry, NGOs) in the presentation of stakeholders' views under each option, which could perhaps be due, in part at least, to the absence of a public consultation (see Annex VII for details, IA, p. 265).

Monitoring and evaluation

The IA report envisages the following measures to make sure the objectives set in the proposed regulation (including the operational objectives) are met:

[3] Evaluation of Regulation (EC) 2003/2003 relating to Fertilisers, Final Report 2010
[4] Study on options to fully harmonise the EU legislation on fertilising materials, including technical feasibility, environmental, economic and social impacts, European Commission, 2012

- an ex-post evaluation and a new SME consultation 5 years after the entry into force of the new regulation. The focus of this evaluation would be on the evolution of municipal waste treatment technologies and the expected increase in waste recovery installations (operational objectives 1 and 3);

- an ex-post evaluation focusing on the number of patent registrations for new sustainable products for industrial processes before and after implementation of the new regulation (operational objective 4);

- use of enforcement indicators (as examples the IA report uses the number of products checked, the number of non-compliant products among those checked, or the type of non-compliance)(operational objective 2) (IA p.67);

- analysis of the information reported by Member States under Council Directive 2001/81/EEC on national emission ceilings for certain atmospheric pollutants including ammonia emissions. This information is meant to indicate whether the new harmonised labelling system proposed under the new regulation has indeed 'allowed end-users (farmers, growers and the general public) to make conscious choices based on the intrinsic product quality indicated on the labels' (operational objective 5) (IA p.69).

However, it should be noted that the proposal itself does not include these detailed considerations regarding the mechanisms for evaluation. According to the Explanatory Memorandum, the European Commission 'will assist and monitor Member States' implementation of the Regulation. It will also analyse the need for guidance, standards or schemes proving sustainability of fertilising products, thus allowing sustainability-claims on the product labels' (Explanatory Memorandum p.9).

Commission Regulatory Scrutiny Board (RSB)

The RSB reviewed the draft IA twice and issued two reports in January 2014 and July 2014 respectively. The latter report was positive but recommended revising several significant points. For example, it recommended a better presentation of stakeholders views and, especially, an explanation as to why only targeted consultations were carried out and not an open general consultation, and better presentation of the policy options, especially Option 4 and its three variants. The final IA report addresses these recommendations in a rather general fashion without providing exact answers to the RSB questions. For example, as far as the stakeholders consultations are concerned, the IA does not explain explicitly and at length how stakeholders' views were taken into account for every option discussed (see the section on stakeholders of this appraisal), nor why an open public consultation was not conducted. The IA report would have benefited greatly had it addressed these RSB recommendations in more detail.

Coherence between the Commission's legislative proposal and IA

The Commission's legislative proposal largely appears to follow the recommendations expressed in the IA. As the Explanatory Memorandum explains, the final proposal corresponds to Option 5, coupled with the variant of optional harmonisation, chosen as the best policy choice because 'it would lead to administrative simplification' and 'ensure flexibility' (p.9). No details on implementation and monitoring as envisaged in the IA were included in the legislative proposal. As far as the limits on cadmium levels are concerned, the proposal differs from the preferred Option 4 in the IA part 2 (see Box 1, below).

Conclusions

Overall, the IA has managed to present well the problem and policy options of a complex policy area. The explanation of the need to revise the existing regulation is clear, as are the policy choices. Nevertheless, it is not very clear from the content and structure of both parts of the IA IA report just how firmly this proposal is integrated into the Circular Economy agenda which it is meant to help implement. Furthermore, the IA does not always provide clear information regarding the effects on SMEs, and the low numbers of responses in the SMEs test raises the question of the extent to which it is representative. Finally, both parts of the IA report refrain from

giving more concrete timelines other than saying repeatedly 'in the long run'. The presentation therefore suffers from a somewhat vague timeframe throughout the analysis.

Annex ***Policy options for limits of cadmium in phosphate fertilisers*** ***(IA Part 2****, pp. 26-27)*

Option 1 No Action

According to the IA report Part 2, if no action is taken, i.e. there is no EU limit on cadmium content and not all Member States set appropriate limit values, there is a risk that the level of cadmium in EU agricultural soils would increase in the long run.

Option 2 Market incentives

The IA report presents several sub-options to provide market incentives (taxation or subsidies) for increasing the use of low-cadmium containing phosphate fertilisers. Adopting either of these options would make decadmiation more attractive for the industry. However, the IA concludes that this option is less preferable because of an expected increase in price due to taxation, and the difficulty to establish subsidies at EU level.

Option 3 A new regulation setting an upper limit of 60 mg cadmium/kg P2O5 in phosphate fertilisers while allowing Member States to impose a limit value of 40 or 20 mg cadmium/kg for the placing of the market and use depending on the conditions prevailing in their territories.

The IA concludes that setting an upper limit at 60 mg would lead to a reduction of new cadmium input into agricultural soil; however, further reduction would depend on the number of Member States using the flexibility of this option to set the individual limits to 40 or 20 mg.

Option 4 A new regulation setting a community limit value for cadmium content in phosphate fertilisers at 60 mg cadmium/kg decreasing over time to 40 and eventually to 20 mg cadmium/kg if decadmiation becomes available on industrial scale.

Full implementation of this option would lead to a decrease in cadmium concentration in soil in the long term and hence a clear reduction of risks to health and environment. The feasibility of this option would depend on the availability of the decadmiation technology on an industrial scale.

Option 5 A new regulation setting an upper limit of 40 mg cadmium/kg P2O5 in phosphate fertilisers while allowing Member States to impose a limit value of 60 or 20 mg cadmium/kg for the placing of the market and use depending on the conditions prevailing in their territories.

This option would reduce cadmium levels throughout the EU. However, cadmium accumulation might still continue in some Member States, depending on how they used the flexibility of this option.

The IA report Part 2 concludes that Option 4 is the preferable option. The legislative proposal, however, prescribes the limits without the condition of availability of technology for decadmiation on industrial scale.

This note, prepared by the Ex-Ante Impact Assessment Unit for the European Parliament's Committee on the Internal Market and Consumer Protection (IMCO), analyses whether the principal criteria laid down in the Commission's own Impact Assessment Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work.

To contact the Ex-Ante Impact Assessment Unit, please e-mail: EPRS-ExAnteImpactAssessment@ep.europa.eu

Manuscript completed in July 2016.