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WORKING PAPER

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From:	Presidency
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	Presidency flash - WP meeting on 8 October

1 October2018

On Article 4

Economic operator responsible for compliance

Article 4 of the Commission proposal 2017/0353(COD) has been questioned by most of the delegations pointing out that just an easier access to information would not justify the efforts: actual measures could still not address an actor in the EU. Consequently, the Presidency has proposed to amend the article by extending the responsibility beyond the provision of documentation. While the cosmetics and medical devices legislation includes a similar element, it should be noted that our proposal is by far not so far reaching (e.g. no joint and several liability of authorized representative and manufacturer and no product registration), and thus adapted to the usually lower level of risk of the legislation in the scope of this proposal.

Nevertheless, some delegations have indicated their reservation about this approach, requesting more information on the possible implications. This paper discusses the concerns raised. They are cited at the beginning of each chapter.

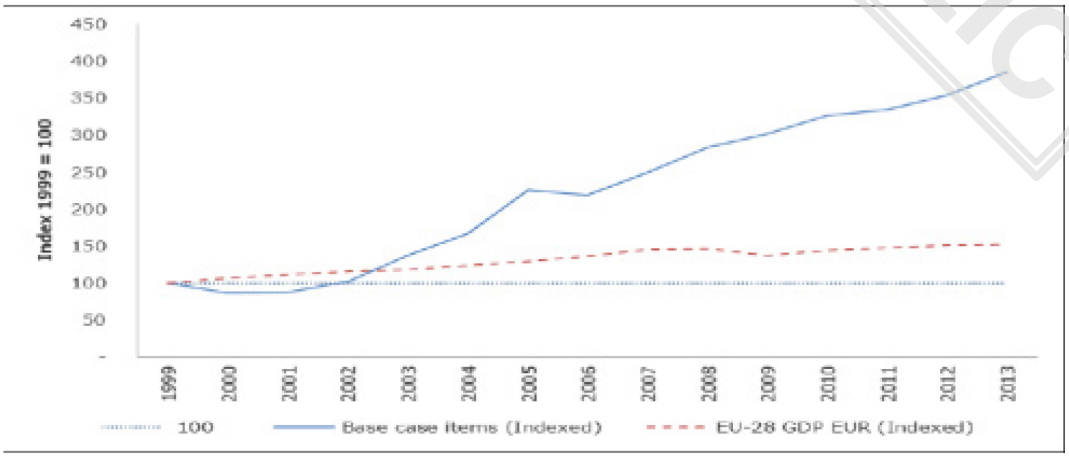
Key amendments compared to 2017/0353(COD)

Person responsible for compliance information	→	Economic operator responsible for compliance
Keeping the documentation	→	unchanged
Providing MSAs with information necessary to demonstrate conformity	→	unchanged
Cooperating with MSAs	→	unchanged
Remedy non-compliance	→	new
Contact on website	→	only for online sales

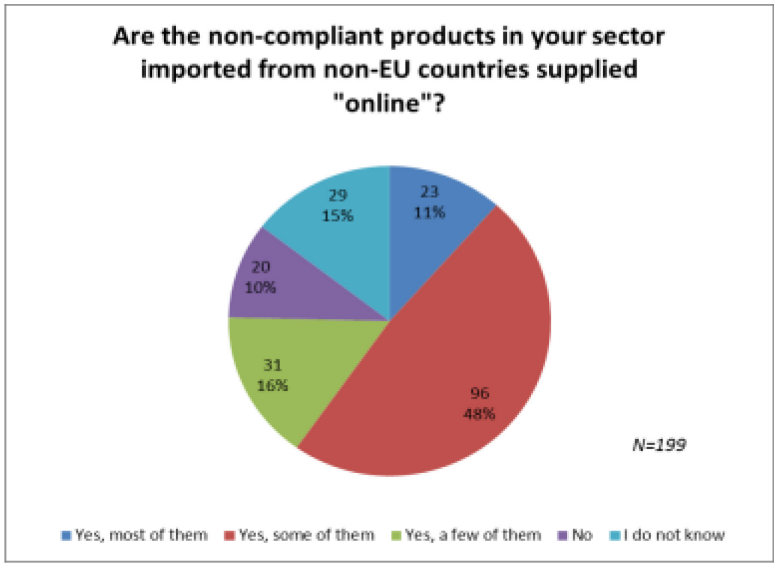
1. Actual scale of the problem

"Number and percentage ratio of non-compliant products made available on the EU market by direct selling from third countries"

According to the impact assessment and COM's presentation WK 8195/2018:



Growth in international receipts of small consignments from outside the EU vs GDP growth from 1999 to 2013



- 75% see direct supply from third countries as source of non-compliant products
- 200 Mio small consignments, value 4.6 billion EUR

The report of German Customs (2012) provides the following facts:

- 79% of 13.500 checked consignments included non-compliant products among them 86.700 electrical equipment, 93.500 toys, 135.100 sun glasses, and 100.000 pyrotechnics.

Though customs checks are risk based, it is safe to assume that the number of non-compliant products slipping through and ending up on the EU market is in any case considerable.

Although market surveillance investigation campaigns on products sold online are not systematically or regularly conducted in all product sectors and MS, results reported from past individual campaigns and projects nonetheless point to increasing trends of non-compliant and illegal products offered via e-commerce channels (Impact Assessment p. 645).

3. Trade aspects

"Costs for third country sellers, presumed deterrence from EU market, and narrower supply"

Costs for third party sellers touch one of the objectives of the whole proposal, and its implementation with this article: fair competition. Economic operators have to provide for the case that actions are needed to remedy a case of non-compliance. Obviously, a traditional economic operator situated within the EU has to bear these costs (e.g. for insurance). When a third country seller has to bear the same costs, a level playing field is ensured.

Regarding the amount, it is plausible that costs will depend on the risk that the product might turn out as non-compliant. This market force provides a positive feedback promoting products with a better compliance record, and is thus in line with the objectives of the proposal.

A reduction of choice of products seems highly unlikely, as a market of 500+ Mio. is correspondingly attractive. E.g., there is no evidence of insufficient supply of cosmetic or medical products. Furthermore, gaps will be filled by competitors in a free market economy.

As COM has demonstrated under "Assessment of possible side effects" on p. 660 of the impact assessment, it is not very likely that products are by chance compliant

with EU-legislation. Thus, products need to be designed specifically for the EU market. It is then highly unlikely that a manufacturer would be discouraged from placing a product on the market after having taken all the necessary steps to design a product that meets the EU requirements.

"Compatibility with WTO"

As regards the WTO legal system, it must be remembered that this is not a global regulatory harmonisation system.

Under the GATT, parties should generally treat each other the same way (Most Favoured Nation principle, Article I); they are free to maintain their own legislation, but they have to do it in a non-discriminatory manner (Article III.4).

Article III:4 requires parties to accord imported products a "treatment no less favourable", ensuring equality of opportunities. Additional costs connected with the person responsible for compliance do not place such operators in a position that is less favourable than that of domestic operators, who face comparable costs (e.g. insurance).

In addition, parties must not impose quantitative restrictions (Article XI). Moreover, even in the event of a breach of one of those provisions, Article XX(d) allows parties to maintain measures "necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement".

As for the TBT Agreement, conditions relating to the presence of a representative on the territory of a party could not be described as a "technical regulation". That term is defined in Annex I to the TBT Agreement as a "Document which lays down product characteristics or their related processes and production methods…"

Likewise, such conditions could not be described as a sanitary or phytosanitary measure within the meaning of Annex I to the SPS Agreement.

It should also be noted that the basic concept stems from Decision 768/2008/EC and is unchallenged since 10 years: For most product sectors, the requirement for a person responsible for compliance merely updates this existing legal framework, which already put obligations related to compliance on economic operators, but which no longer achieved this effect due to new types of supply chains.

Concrete precedents already exist in Article 5(1) of Regulation 1223/2009 on cosmetics, Article 11(5) of Regulation 2017/745 on medical devices and Article 11(5) of Regulation 746/2017 on IV medical devices.

In conclusion, this is not an issue of WTO law.

4. Enforcement in practice

"Persons obliged mandating authorized representatives are established outside the jurisdiction of the EU"

While EU authorities have no direct access to a manufacturer in a third country, measures against its products at the border can be just as effective as penalties.

According to Art. 4(4), the responsible person's contact data need to be on the packaging; customs checks them according to Art. 27(1)(d). What should not be underestimated is self-regulation of the market, by means of unfair competition law. This effect has been seen in regard of the authorized representatives of the medical devices sector.

For MSAs, checks throughout the supply chain, including at custom controls are considerably facilitated. The indication of the responsible person makes it easier to contact, spending less time/costs on tracing traders and evidence gathering. If it is absent, it is an indication that the manufacturer may not be aware of its obligations on EU requirements. Market surveillance authorities can choose how to follow-up: using other means to contact the manufacturer, analyse the product, etc. before deciding what to do with the product.

In addition, already today for most products, the manufacturer, importer or authorised representative has to be indicated, so it should be seen as an update of that requirement. Enforcement in practice should normally thus be quite similar to enforcement of those current requirements. For major sectors, e.g. electrical apparatus, the requirement is in force since 2½ years, without negative feedback from industry, but with apparent benefit for surveillance activities.

Indication online facilitates online checks on products offered to EU consumers without requiring physical access to the product.

"Circumvention of the obligation by mandating letterbox companies"

Art. 4a(4) includes a requirement that an authorized representative shall have the appropriate means available to be able fulfil its tasks, thus providing leverage for MSAs in case of doubts. Experience of nearly a decade in the medical devices sector show that letterbox companies did not become a notable problem.

5. Impact on EU customers

"Consumer might end without product and money when products are seized at customs"

Market surveillance is done to protect consumers and other end-users from unsafe and non-compliant products. Art. 4 is a tool for authorities to improve market surveillance, especially of product sold online. It thus increases consumer protection. We would not see it as a problem, but as a solution, when we can prevent a consumer being endangered by a non-compliant product.

The concern also implies that consumers are not aware of legal requirements and possible risks involved when doing business. However, even now consumers have to and can take educated purchasing decisions: they need to consider 35.000 CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora) listed species, be aware of tobacco, plant and pharmaceutical restrictions, and face civil and criminal prosecution in case of acquiring counterfeit products. Consumer are well aware that an economic advantage might result in a higher risk.

6. Summary: What to expect for MSAs and businesses

- MSA can effectively limit the consequences of non-compliant or dangerous products from 3rd countries sent directly to end-users or through fulfilment service providers.
- MSA have an economic operator at hand for not only addressing, but also enforcing orders.

- 3rd country direct sellers will be encouraged to actively deal with Union rules, as fulfilment service providers or authorized representatives will require such diligence because of their responsibility for compliance.
- This awareness raising effect will result in fewer non-compliant products on the market.
- Economic operators, on the one hand, are responsible for the placing on the market of non-compliant products, and on the other hand, benefit from a level playing field. Consequently, it is only fair, that they contribute to the effort to improve the situation on the market.
- The revision clause Art. 62 will give the opportunity to evaluate the effectiveness of the measure.