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WORKING DOCUMENT

From:	CZ delegation
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	CZ comments on the Compliance and Enforcement Regulation Proposal: doc. WK 10325/18

Comments
of the Czech Republic

to the Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulation (EU) No 305/2011, (EU) No 528/2012, (EU) No 2016/624, (EU) No 2016/425 and (EU) No 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EC, 3012/39/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU a 2014/90/EU of the European Parliament and of the Council

following the meeting of the Council Working Group on Technical Harmonisation (G7)
on 5 – 6 September and 13 September 2018

General comments

We would like to appreciate the effort made by AT PRES to redraft the text of the proposal and to consider the majority of comments submitted by Member States. In general, we can support the proposed changes and we are prepared to contribute maximally to reach a concensual text which, however, will reflect the main concerns of the Czech Republic.

For the time being we still keep a general scrutiny reservation to the whole text, but our approach to the modified text as presented in the document WK 10325/2018 INIT is positive. Nevertheless, we would like to submit the following comments:

Article 2 Scope

The scope of the proposal is defined by the list of legislation in the Annex. We appreciate that some legislation was deleted (e.g. Regulation (EC) No 552/2004, Regulation (EC) No 273/2004) and new items (e.g. Directive 2014/40/EU) have been added.
The document WK 10325/2018 INIT contains a proposal for a new approach to the definition of the scope of the Regulation. The two Annexes are proposed where Annex II covers only motor vehicles and relates to the Regulation 2018/858. The reason is that the Regulation 2018/858 contains specific control requirements and therefore this Regulation should apply only to certain segments of control not covered by the Regulation 2018/858, and it should be specified in the paragraphs 2 and 3 of the Article 2.
Initially we supported this approach, however, after the detailed evaluation of the situation and of possible impact on market surveillance, in particular by the Ministry of Transport as a national competent authority, we consider this approach as problematic. When assessing the proposed legislation, it is necessary to take into account mainly the exceptional nature of the approval of vehicles and their parts. The most of legislation in Annexes deals with the production of motor vehicles, controls of production or controls of compliance rather than market control. From the point of view of the Ministry of Transport, legislation on motor vehicles (Directive 2007/46/EC, Regulation 167/2013, Regulation 168/2013 and Regulation 2018/858) has a certain level of exclusivity and link to each other as regards the process of approval of the type of motor vehicles. Ideally, it would be appropriate to supervise all these rules by the same way. Basically, there is no difference between surveillance of the market with passenger cars, tractors or motorcycles. Thus, now two approaches are considered:
- firstly - due to significant difference of legislation on motor vehicles to separate this kind of legislation and to include it into a separate Annex (Annex II),

- secondly - there is no sense to perform controls of passenger cars in a different way from controls of e.g. motorcycles or tractors.
Since it is currently unlikely that specific legislation covering market surveillance controls of all types of motor vehicles (e.g. motor cars, tractors, motorcycles) should be in place we prefer to cover market surveillance in this area by this Regulation. From this point of view, **we prefer to have one piece of legislation generally covering rules of market surveillance which will be better understood by the supervisory authorities**. **Thus, we prefer to have only one Annex listing all harmonised legislation including legislation on motor vehicles falling under the scope of this Regulation** instead of Annex I and Annex II. In case of listing legislation on motor vehicles into a separate Annex (Annex II) potential changes should be reflected in that legislation as well which seems to be quite demanding and taking into account the discussion on the Regulation 2018/858 it is not a tactical move. Moreover, paragraph 4 is still remaining in this Regulation which refers to the application of the principle *lex specialis*.
In case of motor vehicles we have the analogy in medical devices. Legislation on medical devices is listed in the Annex I (Regulation (EU) 2016/1628, Regulation (EU) 2017/745) and it contains provisions on controls of these products as well. It has been promised by EC to prepare a new guide on relationships of new medical devices legislation and this Regulation (by the way we would like to ask EC to confirm this promise and indicate when we can expect it) and such a guidance should also be prepared for the area of motor vehicles.
Last but not least we believe that the clarification of relationship between this proposal and GPSD is still needed. **At the last meeting a possible inclusion of GPSD was mentioned, however, we cannot support it**. GPSD is a general framework legislation applicable for all products, not only for harmonized area. Moreover, it seems to us that in such a case the scope of this Regulation would be extended.

Article 3 Definitions

It is proposed to include a new definition of a „product", the text of which is taken from the 2013 proposal on market controls. **We consider this definition redundant and confusing** since legislation in the Annex contains separate definitions of products. The definition of a „product" will be logic in case of a general regulation on market surveillance or in case of a general scope of a regulation, however, the scope of this Regulation is defined by legislation in the Annexes.

New definitions of „risk", „product presenting a risk" a „product presenting a serious risk" have been included, and the definitions of a „serious risk" is eliminated. Despite clarification of a „risk" we need to point out links between GPSD and possible implications. The abovementioned definitions are of a genaral nature and primarily they should be included in the framework legislation dealing with product safety in general which is just GPSD. Thus, **we require unequivocal clarification of the relationship between this Regulation and GPSD**, and if there is an intention to amend the definitions in GPSD as well. Moreover, the Regulation refers to a „serious risk", and not to a „risk". We would like to mention that e.g. Regulation on medical devices (2017/745) includes the definition of a „risk" which is a little different than the text proposed in this Regulation (Article 2(23): *'risk' means the combination of the probability of occurrence of harm and the severity of that harm*;), and this aspect should also be considered.

Article 12 Activities of market surveillance authorities and use of findings

We can agree with the reformulated text of the Article, however, we propose following amendments:

ad paragraph 6 (**„***Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls* ~~*on the basis of*~~ ***based on*** ~~*a representative*~~ ***an adequate*** *sample* ***in accordance with the national market surveillance strategy referred to in Article 13****."*)

We propose to amend it as follows:
„(6) Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks ~~and, where appropriate~~, physical **or** ~~and~~ laboratory controls **and take samples of products in order to detect non-compliance and obtain evidence.** ~~on the basis of~~ **based on** ~~a representative~~ **an adequate** ~~sample~~ **in accordance with the national market surveillance strategy referred to in Article 13**.“
(*Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks, physical or laboratory controls and take samples of products in order to detect non-compliance and obtain evidence*.)
or
„(6) Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks ~~and, where appropriate~~, physical **or** ~~and~~ laboratory controls. ~~on the basis of~~ **based on** ~~a representative~~ **an adequate** ~~sample~~ **in accordance with the national market surveillance strategy referred to in Article 13**.“
(*Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks ~~and, where appropriate~~, physical or ~~and~~ laboratory controls.*)

The proposed text prefers one type of controls - documentary checks which is hardly acceptable. We are of the opinion that it is up to a market surveillance authority to decide, based on evaluation of a given situation, which type of control is the most appropriate. We also consider as inappropriate to link sampling to national strategies (Article 13) which is prepared for a longer time but sampling (plans of sampling) has to reflect a real situation on the market. An approach to sampling might be changed during a short time for different reasons and, if linked to a national strategy, a level of flexibility of market surveillance authorities can be limited in this case. Moreover, an adminsitrative burdes of authorities will increase due to a need to update the national strategy. Thus, we propose to delete the last part of the paragraph, or if necesary to keep a reference to samplig, to include a more general text justifying sampling as such.

ad paragraph 7 (*„In deciding what checks to perform and on what scale, market surveillance authorities shall* ***follow a risk based approach*** *tak****eing*** *into account~~,~~ in particular~~, established principles of risk assessment~~* ***the possible hazards associated with the product and its number on the market,*** *~~and~~ complaints* ***and other information***.“)
We propose to delete the words „and its number on the market“ since it is confusing and may cause problems in its interpretation. We cannot agree that a number of products on the market is a risk factor, and moreover, it is unclear how and where such kind of information should be found and how it should be verified. In principle, an extent of the use of a product, a way how it is used or its availability on the market should be part of risk assessment anyway.
Thus, we propose to amend it as follows:
„(7) In deciding what checks to perform and on what scale, market surveillance authorities shall ***follow a risk based approach*** *tak****eing*** *into account~~,~~ in particular~~, established principles of risk assessment~~* ***the possible hazards associated with the product~~ and its number on the market~~,*** *~~and~~ complaints* ***and other information***.“
(*„In deciding what checks to perform and on what scale, market surveillance authorities shall follow a risk based approach taking into account in particular the possible hazards associated with the product, complaints and other information*.“)

ad paragraph 10 (*„Market surveillance authorities shall actively participate in administrative coordination groups according to Article 32(6) to ensure communication and coordination with their counterparts in other Member States.“)*
We propose to delete this paragraph since this activity is not linked to market surveillance as such. Who will represent a Member State in administrative coordination

groups is up to the decision of each Member State. This provision might cause problems if more than one authority is involved in a certain issue. Moreover, it seems that this provision overlaps with the Article 32(6), according to which *„administrative cooperation groups of market surveillance authorities (ADCOs), set up by the Member States for the implementation of the different parts of Union harmonisation legislation are composed of representatives of the national market surveillance authorities".* We believe that the right and sufficient place to express appropriateness of the participation of market surveillance authorities at ADCOs meetings is the Article 32(6).

ad paragraph 12 (*Products deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be non-compliant by market surveillance authorities in another Member State, unless evidence to the contrary is provided or a Member State has raised objections in accordance with the applicable Union safeguard procedure*.)
We would like to get assurance that a product assessed as non-compliant in a Member State does not need automatically be considered as non-compliant in another Member State but it can be used as an impulse for market surveillance. As a non-compliant product may be considered only such a one that is identical with a non-compliant product in a reporting Member State, e.g., a brand, a lot, date of production, used materials. We believe that some explanation should be included in a relevant recital.

Article 15 Market surveillance measures
ad paragraph 1e (*If a national measure is considered justified, the competent market surveillance authorities in the other Member States shall take the corrective actions necessary in respect to the non-compliant product, and shall enter the related information in the system referred to in Article 34.*)
In our opinion this provision relates to Article 12(12). We would like to get assurance that the same regime will be applied as in Article 12(12).

Article 17 Judicial protection and due process
ad paragraph 4 (*The market surveillance authority shall promptly withdraw or amend any measure, decision or order where the economic operator can demonstrate that he has taken effective corrective action.)*
We would like to support proposals on the deletion of this provision. The proposed process is in direct conflict with the national legal procedural and administrative rules.

Chapter V
We can agree with the reformulated text, however, we would like to express our view to include the requirement on free sampling. The power of market surveillance authorities to take samples is mentioned in the Article 14(3)(o) (*„powers to carry out on-site inspections, including entering premises, physical controls, and acquire product samples").* **We cannot agree that sampling should be generally free of charge** but sampling should always be somehow justified. According to the National Control Code there is an obligation to pay a financial compensation, however, there are possible exceptions from this obligation. The free sampling is possible if a taken sample is not in line with legislation, or if a taken sample is returned to a controlled person, or if a controlled person has refused to take a sample back, or if a controlled person does not require to return a taken sample. Moreover, taking free sampling might be possible only for products falling under the scope of this proposal. The consequence of inclusion free sampling in this Regulation is establishing two regimes for sampling of non-food products. We believe that it should be under a decision of each Member State if sampling is free in all cases and to include such a power into the national legislation. If necessary, this aspect can be clarified in the relevant paragraph of Recital.
As regards the Article 20 Testing facility support as it was presented at the session of the working group **we support the proposed PRES approach**. We believe that the text reflects the main

interest of some Member States, i.e. unsufficient testing capacities for the control purposes. We do not have any specific proposals to this Article, but we are prepared to consider any possible proposals submitted by other Member States or EC.

Article 26 Controls on products entering the Union market

The Article 26 sets up requirements on controls of products entering the EU market and obligations for customs services. As regards the obligations on submission of statistical information we draw your attention to the fact that information between customs services of Member States are transferred by means of existing IT tool and thus these provisions seem to be redundant. Moreover, statistic data required by the paragraph 7 cannot be in fact found out and if it will be the case it will result in further unjustified administrative burdens. The requirement to submit yearly report by customs services seems to be redundant if the EC previously stated that it will be possible to take all necessary information of the IT system. **We propose its deletion**. If there is possibility to extract data from IT system, why will it be necessary to submit yearly reports just by customs authorities if other market surveillance authorities are not obliged to do so? That is why **we consider the paragraph 9 also redundant**.

Article 27 Suspension of release for free circulation

We would like to ask for explanation of this Article and for some examples of its practical application. If a product is under a custom procedure it is up the customs services to proceed in line with the Union Custom Code. As for the paragraph 3 we need explanation how market surveillance authorities find out that an imported product is not in compliance with relevant legislation or is unsafe. If a custom procedure has already started a product is under customs controls in line with Union Custom Code. The question is how market surveillance authorities will justify a possible request on suspension of its release into free circulation if a products is still under custom controls. We would like to remind that the Union Custom Code does not define the term „suspension of procedure“, and since there is link to customs procedures the terminology should be identical. We will be able to inform you about our position after we receive the required explanation.

Article 28 Release of products

We would like to ask for explanation of this Article and for some examples of its practical application. Namely we would like to know why the application of Union Custom Code is not sufficient. We also draw your attention to the last sentence at the letter b). The sentence in fact means that a product is released into free circulation even if it is not considered to be in compliance with EU harmonised legislation but in such a case a control is pointless. If market surveillance authorities do not respond in required period it is supposed that a product is in line with relevant harmonised legislation. We will be able to inform you about our position after we receive the required explanation.

Article 30 Refusal to release

In our opinion the use of the Article 197 of the Union Custom Code is impossible. This Article refers to destruction of goods but in case of Article 30 reasons for destructions of goods will not be fulfilled. **We propose the deletion** as it has been done in Article 27 (deletion of its paragraph 4).

Article 31 Union Product Compliance Network

ad paragraph 2 (*The Commission shall support cooperation between public authorities and in particular market surveillance authorities via the Network and participate in the meetings of the Network, its sub-groups and the ADCOs*.)

This text sets up the obligation for EC, and thus, **it should be shifted to the Article 33** which speaks about the Tasks of Commission.

ad paragraph 3 („*To perform the tasks set out in Article 32a, the Network shall be assisted by the Commission by means of an executive secretariat that provides technical and logistic support to the Network, to its sub-groups, and the ADCOs.*“)
In this paragraph the abbreviation of ADCOs is used for the first time without any explanation. We propose to introduce the legislative abbreviation here and then to use it consistently in the following text:
„*To perform the tasks set out in Article 32a, the Network shall be assisted by the Commission by means of an executive secretariat that provides technical and logistic support to the Network, to its sub-groups, and* ***the administrative cooperation groups of market surveillance authorities („ADCOs“)***.“

Article 32a Tasks of the Network
ad paragraph 2(d) („*to take up any other issues in activities under the purview of the Network;*“)
We propose to shift this text at the end of this paragraph just after stating of all specific tasks which should be fulfilled by the Network.

ad paragraph 2(p) („*to provide advice and assist the Commission with issues related to the further development of RAPEX and ICSMS*“)
The system ICSMS is specifically mentioned in the paragraph 2(p) but it is the Article 34 that deals specifically with information and communication system. However, the Article 34 does not explicitly refer to the ICSMS. Thus we believe that text „and ICSMS“ s**hould be replaced by** the wording „*and information and communication system according to the Article 34.“* Further, this provision refers to the RAPEX, however, RAPEX is established under GPSD and its management, operation and development belongs under a different administration, and national contact points have been established in each Member State. Thus, it seems that there is a certain discrepancy with GPSD. Thus, **it is necessary to clarify the relationship between this Regulation and GPSD**.

Article 32b Tasks of administrative coordination groups
ad paragraph 2 („*ADCO meetings are closed meetings frequently dealing with confidential issues. However, ADCOs may organize open sessions to exchange views inviting on a case-by-case basis stake holders such as organisations representing the interests at Union level of industry, small and medium-sized enterprises, consumers, laboratories, standardisation and conformity assessment bodies.*“)
We propose to simplify the text as follows:
„(2) ADCO meetings are closed meetings ~~frequently dealing with confidential issues~~. However, ADCOs may organize open sessions to exchange views inviting on a case-by-case concerned stakeholders. ~~basis stake holders such as organisations representing the interests at Union level of industry, small and medium-sized enterprises, consumers, laboratories, standardisation and conformity assessment bodies.~~“
(„*ADCO meetings are closed meetings. However, ADCOs may organize open sessions to exchange views inviting on a case-by-case concerned stakeholders*.“)
The meetings should be closed in principle and there is no need to justify it. We are not in favour to list stakeholders who might participate at the meeting even if not exhaustive. **We prefer a general text** and it will be up to the ADCOs and their programmes which stakeholder/stakeholders will namely be invited.

ad paragraph 3(a) („*Administrative coordination groups (ADCOs) shall have the following tasks:*
(a) to coordinate the ~~enforcement~~ uniform application of Union harmonisation legislation within their area of competence;“)
We do not believe that ADCOs can have a power to coordinate uniform application of Union harmonisation legislation, since this is the role and responsibility of Member States and EC. **Thus we propose to amend the provision** as follows:

„(3) ~~Administrative coordination groups (~~ADCOs~~)~~ shall have the following tasks:
*(a) **to support (or to facilitate)** ~~coordinate~~ the ~~enforcement~~ uniform application of Union harmonisation legislation within their area of competence;"*

(„ADCOs shall have the following tasks:
*(a) **to support (or to facilitate)** the uniform application of Union harmonisation legislation within their area of competence;")*

ad paragraph 3(e) (*„to establish and coordinate common actions such as cross-border **(joint)** market surveillance activities;"*)
It seems that this text overlaps with the provision of the Article 32a(2)(h) which says almost the same *(„(h) to organise cross-sector joint market surveillance and testing projects and define their priorities;");* consequently we suggest its deletion.

Article 61
We support the new text of this Article as proposed in the document WK 10325/2018 INIT. We do not see any benefit from the new inserted text – „„**according to national legislation**,". During the discussion on 13 September 2018 it was referred to the Regulation (EU) 2017/625 of the European parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation), when it was specifically referred to the Article 139[1]. However, in this case the words „in accordance with national law" are used in a little bit different context. **Thus, we propose to delete** the words „**according to national legislation"**, in the first line of the Article 61(1).

[1] *„Article 139*
Penalties
1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by 14 December 2019, notify those provisions to the Commission and shall notify it without delay of any subsequent amendment affecting them.
2. Member States shall ensure that financial penalties for violations of this Regulation and of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices, reflect, in accordance with national law, at least either the economic advantage for the operator or, as appropriate, a percentage of the operator's turnover."