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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 11296/18

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 3 and 8 October 2018

General comments

The comments bellow relates to the working document WK 11269/2018 INIT which were discussed during the last two meetings of the Council Worging Group G7 on Technical Harmonisation.

For the time being we still keep a general scrutiny reservation to the whole text as raised at the very beginning of the discussion on the proposal. Despite a positive approach to the modified text as presented in the document WK 11269/2018 INIT, we would like to submit the following comments (some of them are included in the document WK 11320/2018 INIT of 27 September 2018):

Article 1 and following:

We would like to highlight problems with the scope in the document WK 11296/2018 INIT as a consequence of using non-uniform terminology. Article 1(1) refers to the "Union harmonization legislation listed in Annex I to this Regulation" and the legislative abbreviation "Union harmonization legislation" that has been deleted but it is subsequently used in the text, e.g. Article 3(4), Article 12(8), Article 12(9), Article 3(13), Article 3(19), Article 4(4), Article 4a(1), Article 6(1), Article 6(2), Article 8, Article 13 or Article 15(3). The collocation “Union harmonisation legislation set out in the Annex I to this Regulation” is used in some articles, e.g., Article 10a(2), Article 12(8) or Article 14(1). The Article 4(1) and 15(4) refers to “legislation listed in Aneex I”. The Article 2(2) states the other term - "Union harmonization legislation set out in Annex II". This results in a confused scope, and it is not clear which provisions of this regulation will be applied to what legislation.

E.g. Article 4(1) refers to "a product in the scope of the legislation listed in Annex I ...", and logically it might be considered as another version of the "Union harmonization legislation set out in Annex I to this Regulation", but in the Article 4(4) it is refered to "Union harmonization legislation" where it is not clear whether only Annex I or also Annex II or, in general, any product-specific legislation is meant. An example of another interpretation problem is the Chapter IV. The new Article 10a)(2) speaks about on “Union harmonisation legisaltion set out in Annex I”, the Article 12(8) also refers to the "Union harmonization legislation set out in Annex I", but in the Article 12(5), reference is made to "Union harmonization legislation". This means that a possibility for market supervisory authorities to take into consideration certificates and test protocols will be applied to the whole harmonized sphere, but in the case of the obligation to establish appropriate procedures, this obligation will apply only to the legislation listed in Annex I. Similar problems of interpretation are also found in other cases such as Article 14 or Article 15. We require to define scope unequivocally and to clearly explain as the scope is an essential aspect affecting the clarity of

the entire legislation. In the case of Chapter VII, the scope of both the harmonized and the non-harmonized sphere is expanding, which we consider to be nonconceptual and contrary to the title of the draft regulation.

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.

The scope has to be clearly defined and has to be unequivocal (see comments to the Article 1).

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.

We would like to comment the definition under the point 17 "voluntary measures" the text of which says that voluntary measures are "*any* ***a*** ~~*measure*~~ ***corrective action*** ~~*carried out by an economic operator to end the non-compliance of a product, without prior intervention of*~~***, which is not the result of an order given by*** *a market surveillance authority*", however the amended text raises a question who can take voluntary measures. It is generally understood that „voluntary measures" are under responsibilities of economic operators.

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.

In the paragraph 7 „voluntary measures" are defined as „~~*any*~~ ***a*** ~~*measure*~~ ***corrective action*** ~~*carried out by an economic operator to end the non-compliance of a product, without prior intervention of*~~***, which is not the result of an order given by*** *a market surveillance authority*; " is a little bit confusing, since in our opinion only an economic operator may adopt a voluntary measures. Moreover, it is a question whether „voluntary measures" can be regarded as „corrective actions".

Article 4b Obligation of cooperation

ad paragraph 1 (*„Economic operators shall cooperate with market surveillance authorities regarding actions which could prevent or reduce risks that are caused by products made available by those operators."*)

We are not sure why economic operators are obliged to cooperate only in case of prevention or reduction of risks. We believe that it should be clearly stated that this obligation relates also to other aspects of public interests. Thus we propose the following text:

„Economic operators shall cooperate with market surveillance authorities regarding actions which could prevent or reduce risks or any other aspects of public interests that are caused by products made available by those operators."

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 3 (**„***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 based on an adequate sample in accordance with the national market surveillance strategy referred to in Article 13."*)

We propose to amend it as follows:

*„**(3)** 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.** ~~**based on an adequate** sample **in accordance with the national market surveillance strategy referred to in Article 13**.“~~*

or

*„**(3)** 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. ~~**based on an adequate** sample **in accordance with the national market surveillance strategy referred to in Article 13**.“~~*

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 5 („*Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates*.“)

We have objections against the obligation set by this paragraph. We do not deny that documents submitted by economic operators should be considered, but it still should be a possibility for market surveillance authorities to do so. That is why we propose the following text:

(„(5) *Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an accredited conformity assessment body, market surveillance authorities **may consider** ~~shall take due account of~~ such reports or certificates*.“)

ad paragraph 7 (*„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 9 (“*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.

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.

Chapter VII

As results from the modified text of the document WK 11296/2018 INIT the scope of this Chapter has been extended to the non-harmonised area as well. We consider the extension of the scope as nonconceptual and contrary to the title and focus of the draft regulation. So far there was discussion aimed to market surveillance in the harmonised area only, and at the final stage we start disucussion on market surveillance in non-harmonised area, and moreover, only in customs controls. The title of this draft is "*Proposal for a 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 Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/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 and 2014/90/EU of the European Parliament and of the Council",* which refers only to *„Union harmonisation legislation on products".* We cannot agree with the explanation that the reason is cancellation of the Regulation (EC) No. 765/2008, however, it is not a true statement since the Regulation (EC) No. 765/2008 is not deleted by this draft Regulation, only certain provisions are to be deleted. The provisions which should be deleted were mentioned in the new inserted Article 63a, but this Article is proposed to be deleted as well, and reference to the deleted parts of the Regulation (EC) No 765/2008 should be mentioned under the Article 38 Applicability.

We are of the opinion that the solution would be to refer only to the deletion of the Articles 15 – 26 of the Regulation (EC) No 765/2008 and to keep the Articles 27 – 28 which refer to *Controls of products entering the Community market* applicable to the customs controls in non-harmonised area.

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. The requirement to submit yearly statistical data seems to be redundant if the EC previously stated that it would be possible to take all necessary information of the IT system. If there is possibility to extract data from IT system, why will it be necessary to submit yearly data just by customs authorities if other market surveillance authorities are not obliged to do so? On the other hand we agree that the report should be prepared by the EC. We do not support the paragraph 9 and we propose its deletion. We are of the opinion that it should be clearly stated in the basic legislation which data have to be submitted.

Article 27 Suspension of release for free circulation

The paragraph 1(e) includes the term „serious risk" that is specified („*it poses a serious risk to health, safety, the environment or any other public interest referred to in Article 1)*. However, a „serious risk" is not defined by this Regulation. The paragraph 3 refers only to a „serious risk" without any further explanation, and a question raises whether there is any difference and if it is the case, what it is about. The paragraph 4 establishes an obligation to communicate by means of „*the system referred to in Article 34*", in other words by means of the ICSMS. However it is mandatory only for the controls in the harmonised area, and more precisely only legislation listed in the Annex I. If the scope of customs controls is extended to the non-harmonised area the customs authorities will be obliged to submit by means of ICSMS all information, and thus ICSMS will be extended to the non-harmonised area as well. The issue for clarification is whether customs authorities will be obliged to enter information only from harmonised area, and then it is a question how results from non-harmonised area will be communicated. And if customs authorities will be obliged to enter results both from harmonised and non-harmonised areas we need an explanation why it is applied only for custms authorities and why there should be a difference between customs authorities on one side and other market surveillance authorities on the other side.

Article 31 Union Product Compliance Network

ad paragraph 2 *(„The purpose of the Network is to serve as a platform for structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union making market surveillance activities more effective.")*

We can agree with the modified text, however, we would like to ask for including of the reference to the "public authorities" as it was in the previous document (*„The purpose of the Network is to serve as a platform for structured coordination and cooperation among public authorities, ~~between~~ enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union making market surveillance activities more effective.*") since it better reflected the situation in Menber States. The part of an enforcement system are, e.g. in the Czech Republic, also public authorities which do not perform directly controls on the market but they can play other roles in the systém.

Article 32a Tasks of 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**.

ad paragraph 2(pp) (*„to define and approve processing of collected data as referred to Article 34"*)
We refer to the word „approve" which has too strong connotation, and in principle the Net has no power to obligatory approve anything. We propose …

ad paragraph 2(ppp) (*„to prepare and validate system approvals for the execution by a third country related to pre-export product controls as referred to in Article 35 to ensure that these products comply with applicable Union harmonisation legislation"*)
We cannot agree with this formulation since the text may envoke. that the Net has an executive powerment of the Net. To prepare the system of approvals is the role of EC and the Net can dabate it and agree or disagree with the proposals or to submit any recommendation for their modifications. Nevertheles, it is unclear about the possible validation of the system and who will perform such validation. We propose …

Article 33b Role and tasks of administrative coordination groups

Navrhované změny respektují stávající strukturu pracovních skupin IMP-MSG a ADCO pracovních skupin, které fungují úspěšně 10 a více let, a zapojují je do činnosti sítě. Specifikuje se, že zasedání ADCO jsou primárně uzavřená, ale je možné rovněž uspořádat zasedání otevřená za účasti dalších účastníků trhu aktivních v dané oblasti. Dále jsou specifikovány úkoly ADCO, kdy se stanovenými úkoly lze souhlasit s výjimkou ustanovení 32b)(3) e), kdy se zdá, že se jedná o duplikaci ustanovení 32a)(2)h), a ustanovení 32b)(3) a), kdy formulaci „to coordinate uniform application „„" považujeme za nevhodnou a doporučujeme úpravu na „to support or to facilitate uniform application…".

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.~~*"
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;"*

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 33c Role and tasks of the Commission

ad paragraph 2(a0) (*„to keep and make available to the single liaison offices and ADCO-chairs an updated list of ADCO chairs including their nationality and contact information“*)
We would like to ask explanation why it is necessary to mention specifically the nationality of the ADCO chairs.

ad pragraph 2(a00) *(„to support the functioning of Product Contact Points having duties assigned by Member Stated according to Article 6(2)“)*
We do not support this text since Article 6 has been rewritten and there is no reference to the PCP points any more. As correctly stated in the new reworded Article 6 the system of tansferring information is up to the Member States, and among other it may be done by means of PCP points. PCP points are established by the Regulation on Mutual Recognition and they should submit information especially in non-harmonised area. The referrence to the PCP points might lead to a speculation about further extension of the scope of this Regulation or an amendment of its scope. The question arises if a Member States will implement another system then there will be no legitimacy for EC support?

Article 34 Information and communication system

ad paragraph 1a) *(„The Commission shall specify by means of implementing acts the processing that will be applied according to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.“)*
We regard this new text confusing. It refers to the „*the processing that will be applied according to paragraph 1“,* however, any processing is not mentioned in the Article 1. But it seems that the requirements on an implementing acts in this case is purposeless. It is unclear what should be about the objective of this provision.

ad paragraph 6) (*„The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 5 and defining the data to be transmitted in accordance with paragraph 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.“*)
We would like to get explanation about the basic content of the possible implementing act. It is unclear which further details should be included in the future implementing act.
In general we are of the opinion that the legal text should be clear enough and a possible number of implementing acts should be reduced as much as possible, and they should be used only if there is no other possibility. Nevertheless, in the last document the proposals on a number of future implementing acts has increased.

ad paragraph 4a) („*Where relevant for the enforcement of Union harmonisation legislation and for the purpose of minimising risk, customs authorities shall extract from national customs systems information relating to products placed under the customs procedure 'release for free circulation' related to the enforcement of Union harmonisation legislation and transmit it to the information and communication system.“)*
It is unclear which information has to be extracted by customs authorities from customs IT system and transferred to the ICSMS. We would like to ask for explanation why this process is needed if there is a prerequisite for preparing of interface between IT systems.

Article 35 International cooperation

ad paragraph 3a) *(„3a. Approval may only be granted to a third country under paragraph 3 if following conditions are satisfied: (a) audits within the Union demonstrates that products exported*

to the Union from that third country satisfy the requirements set out in Union harmonisation legislation;")
We consider the text of the Article 3a(a) unclear, namely the reference to „audits within the Union". It is no clear which audits are in mind, who will be audited, who will perform audits, how often they will be performed and what will be their results. At the last meeting EC briefly stated that the audits will be performed by EC and customs services will be audited subjects. We need justification of such audits and clarification of the impacts since it seems that there is another administrative burdens for customs services. We do not understand why only customs services should be audited, and why still different (and higher) demands are placed on customs authorities.

Article 36 Financing activities
ad paragraph 2(a) (*„the functioning of the Product Contact Points referred to in Article 6"*)
We do not support this text since Article 6 has been rewritten and there is no reference to the PCP points any more. As correctly stated in the new reworded Article 6 the system of transferring information is up to the Member States, and among other it may be done by means of PCP points. PCP points are established by the Regulation on Mutual Recognition and they should submit information namely in non-harmonised area. The reference to the PCP points might lead to a surmise about further extension of the scope of this Regulation or an amendment of its scope. The question arises if a Member States will implement another system then there will be no legitimacy for EC support?

Article 61 Penalties
We support the new text of this Article as proposed in the document WK 10325/2018 INIT.
(„Article 61
Penalties
1. The Member States shall, according to national legislation, lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented.
1a. The penalties provided for shall be effective, proportionate and dissuasive.
1b. The Member States shall notify those provisions to Commission, by [31 March 2020], and shall notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.")
We cannot agree with the idea to list specific Articles under penalties and also it is hardly to accept the added text *"and of Union legislation listed in Annex I, where that legislation does not provide for penalties"*.

Article 64 Entry into force and application
We cannot agree with the proposal on its application from the date of entry into force which is the twentieth day following of its publication in the Official Journal. We require for two-year period for application as it was proposed originally.