To: [redacted], DG SANTE

From: Plastics Coordination Group[1]

Cc: [redacted], DG SANTE, [redacted], Joint Research Centre (JRC)

24 July 2015.

Dear Bastiaan,

For quite some time now we have been following the development of the Guidelines on Compliance Testing and the corresponding planned amendments to the text of Regulation 10/2011. We have recently become aware of a new draft of the Guidelines being circulated within the Task Force, and have discussed some of the more important points within our recent "Plastics Coordination Group" meeting.

We have identified a number of shortcomings which go beyond merely editorial corrections and/or affect the planned amendment to Regulation 10/2011 and therefore require your risk management input. In the interest of a quick progress on these matters we have decided to contact you directly with our concerns.

Please give due consideration to the following issues we have identified:

1. By far the most troubling provision in the draft Guidelines is the required compliance testing for substances authorized without specific migration limit and therefore subject to a generic SML of 60 mg/kg.

   In our recollection, the assignment of the generic SML of 60 mg/kg to the substances previously referred to as "unrestricted" did not have the intention to impose on these substances the same level of requirements for compliance assessment as for the substances with a listed specific migration limit. Instead, we saw this generic SML of 60 mg/kg as a sort of safeguard clause that can be used e.g. by enforcement authorities when some extraordinary migration level is found in a specific material. In support of our interpretation, we point out that the substances subject to the generic SML of 60 mg/kg are not part of the legal provisions on the Declaration of Compliance as laid down in Annex IV of the Regulation, nor of the Union Guidance on information flow in the supply chain.

   In past discussions during the drafting stage of the Guidance on information flow in the supply chain, and in the early drafting stage of the Guidance on compliance testing, it was repeatedly verbally confirmed to us (by [redacted]) that substances subject to the generic SML of 60 mg/kg were not intended to become listed on the DoC nor to become subject to widespread specific migration testing.

   Currently, the latest draft of the Guidance on compliance testing addresses substances with the generic SML under section 5.2 entitled "screening approaches for specific

[1] Plastics Coordination Group is composed by staff and experts from Cefic-Food Contact Additives (FCA), PlasticsEurope, European Plastic Converters (EuPC) and Flexible Packaging Europe

migration". It offers business operators a method to screen for compliance with the generic SML of 60 mg/kg by carrying out a test for overall migration in combination with the control of highly volatile substances in the context of GMP compliance. This would be a workable solution if not for the recent addition of the requirement that "*the testing conditions required for the specific migration test, were covered by the testing conditions of the overall migration test*".

For a very large number of plastic FCM the relevant OML test condition is 10 days at 40°C, and the relevant SML test condition is 10 days at 60°C. For all these FCM the above provisions would require a separate OM-like test in a non-OM test condition which puts an extra burden on business operators all the more so since none of our historically collected data on OML compliance in the 10d/40°C test condition can be used. This testing burden appears to us to be completely out of proportion compared to any perception of risk to the consumer associated with these substances.

You will understand that an explicit specific migration test for these substances instead of the screening proposal referred to above, is not a viable alternative either.

The solution is simply to return to the agreement previously reached with Mrs. Schäfer that the risks associated with substances subject to a generic SML of 60 mg/kg are sufficiently controlled by a combined requirement of carrying out an OML test *in the relevant OML test condition* together with the control of highly volatile substances in the context of GMP.

Alternatively, we would accept that the generic SML of 60 mg/kg is eliminated from Regulation 10/2011 and any specific issues this limit was intended to address be dealt with by more targeted provisions on a case by case basis.

2. Regulation 10/2011 (in Annex V section 2.1.4) specifies that the contact temperature to be taken into account for frozen storage, when doing calculations with the Arrhenius formula, is 278K (+5°C). It is evident that 5°C is nowhere near actual temperatures in frozen storage. Doing such Arrhenius calculations with a completely wrong temperature leads to distorted conclusions in the draft Guidance on compliance testing, specifically in Table 3 in section 4.4.1.2 where it leads to a 10d/20°C test condition excluding freezing and defrosting inside the package.

   Doing instead the Arrhenius equation with a more correct frozen temperature easily shows that even when allowing an exaggerated full day at room temperature for freezing and defrosting, there is more than enough time/temperature equivalence left in the 10d/20°C test condition to cover the frozen storage.

   Consequently we request that the Regulation be amended to specify a realistic temperature for frozen storage (e.g. -15°C) and that the draft Guidance explains that a 10d/20°C test condition includes freezing and defrosting inside the packaging.

3. We welcome the new formula introduced in the latest draft of the Guidance on compliance testing to account for the equivalency in time/temperature conditions for heating between 70°C and 100°C (e.g. in the context of hot-filling).

There are numerous places in the draft Guidance where the text and examples given do not yet account for this new proposal. Before making the effort of proposing text modifications for all these cases, we would like to understand from you if you support the use of this time/temp equivalency formula and intend to introduce it into the current amendment of Regulation 10/2011, replacing the current wording which refers to "up to 70°C for up to 2 hours, or up to 100°C for up to 15 minutes".

4. Section 2.1.5 of Annex V of the Regulation provides that FCM consecutively subjected to different contact conditions have to be tested by applying the relevant test conditions successively to the same test specimen. In the discussions within the Task Force drafting the Guidance on compliance testing, it has been previously agreed that for screening purposes an acceptable simplification is to use the Arrhenius formula to re-calculate to a single combined test condition. This has been introduced into the draft Guidance for SML screening, but not yet for OML screening. Before making a text proposal for the draft Guidance, we would like to understand from you if you agree with the concept as such, and if you think this can be introduced into the Guidance without amending Section 2.1.5 of Annex V of the Regulation.

5. Previous FCM plastics legislation (Dir. 2002/72/EC and the related testing Directives) contained the concept of a worst case test condition beyond which testing was not necessary. The current Regulation 10/2011 has two rather limited provisions that put a limit on the required testing condition: (i) the provision of allowing 10d/40°C for SML testing for applications longer than 30 days at room temperature in case equilibration has been demonstrated, and (ii) the provision that OML test condition OM5 is the worst case test condition for polyolefins.

   We are in favour of extending the use of the Arrhenius equation to shorter times / higher temperatures, of referring more generally to equilibration also for applications not covered by long term storage at room temperature, and of introducing further general cases of agreed worst case test conditions, also for SML testing. This would help reduce the need for frequent retesting to follow sometimes minor changes to the actual conditions of use.

We hope you recognize that the above comments are made in the spirit of making the FCM legislation more relevant and more workable while maintaining the high level of consumer protection.

We remain available for further discussions on these topics.

Sincerely,

Plastics Coordination Group.