

All

Rather than provide an official FSA response to the consultation, I would like to make a few comments for your consideration (most important points are in red, others are editorial):

Para 1 needs updating following the review of arms length bodies

Para 3, line 9: specified chemical does not seem correct in this context - how about specified material.

Para 14, line 28: surely negative results allow conclusion on the absence (delete presence) of mutagenic potential - but do you also want to say something about positive results?

**Page 9, header V: this was previously "existing chemicals". I appreciate HSE advised on the difficulty of defining existing, but I don't think the change now really captures the issue, which relates to chemicals that we are already exposed to, but for which data might be inadequate or non-existent, and there is no manufacturer to conduct the appropriate tests according to the strategy. This section seems to have been edited back to focus on the testing strategy, whereas there is a need to also comment on hazard assessment, in line with the title of the guidance.**

Para 19, line 25: why not also negative results?

**Para 19, line 31: This has changed and now implies that COM cannot give any advice if the testing strategy has not been completed. This is not helpful for food/environmental chemicals with no sponsor.**

**Para 20: TTC is incorrect. The TTC cited by Kroes et al for genotoxic chemicals is actually 0.15 µg per person per day, which is equivalent to 0.0025 µg/kg bw/day. I believe the confusion is on two levels, intake per person versus intake per kg bodyweight, and the use of a 10-fold higher TTC for genotoxic impurities in pharmaceuticals (1.5 µg per person per day) than that established by Kroes et al. (0.15 µg per person per day) based on the case that medicines have benefits and so a higher risk is acceptable.**

Para 21, lines 22-23 seem superfluous since chemicals with existing data would include novel chemicals that are part way through the strategy.

Para 29, line 28: suggest genotoxicity rather than genotoxicology, plus do not need to include "currently" twice in the subsequent sentence

**Para 33, line 27: previous version included the word "also". As it now reads it suggests that COM is only interested in avoiding misleading positives (i.e. industry-focussed) and not misleading negatives (which would be more protective of public health). FSA has difficulty with this – we should be proportionate, but put the consumer first.**

**Para 36, line 29, use of the word "all" is ambiguous. Does this mean the Ames and MNvit, or also include any random non-standard assays that have been published? Also, if a chemical is carcinogenic, with no clear non-genotoxic mechanism, would Ames and MNvit be adequate, or would you want further reassurance such as absence of DNA adducts?**

Page 18, line 1: delete "subsequently"

Page 22: surely the 4<sup>th</sup> bullet should be either/or rather than neither/nor, but is it needed since it repeats (or contradicts) line 1?

Para 50: "can be routinely be" delete one or other be

Para 57, line 28: why "in negative control cultures (or should it refer to "compared to negative control cultures" inside the brackets?

**Page 30, lines 27-29: This is a very important statement for food/environmental chemicals with no sponsor, but surely it needs to be reflected in the text (e.g. para 19)**

**Para 82: it would be helpful to also consider establishing absence of genotoxic MoA for carcinogens (e.g. ochratoxin A which has been very contentious with conflicting views based on post-labelling and AMS)**

Page 85, line 22 – give full name of ILSI-HESI