Commentary on"Are bioplastics and plant-based materials safer than conventional plastics? In vitro toxicity and chemical composition" by Zimmermann et al.

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Zimmermann et al.[1] asked themselves whether bioplastics and plant-based materials are safer than conventional plastics.
This questionis not meaningful. The authors in the introduction say that bioplastics are marketed as materials less toxic than others and then churn out a lot of results proving this to be false.However, the lower toxicity is not a claim from the bioplastics industry. It would have been sufficient to look at the Assobioplastiche website or talk to the Assobioplastiche officials to know that the industry of bioplastics does not pretend to be “less toxic”, assuming this proposition might haveany meaning, being related to the public health and safety of packaging. Basically, a product is either acceptable or not acceptable in terms of toxicity, as required by the regulations. It is a digital answer. Nobody is involved in a competition to gain the status of “less toxic” than other products.
Bioplastics make two claims, i.e. they claim to be biodegradable and bio-based. Therefore, the article of Zimmerman et al. asks a question that is ill-posed and it seems, in all fairness, a useful rhetorical device to make the conclusions sound as a revelation of the unethical background behind easy commercial slogans.

In Europe, the EU Regulation No 1935/2004 provides a harmonised legal European framework about safety and inertness for all Food Contact Materials (FCMs). In particular, plastic materials (including bioplastics) and articles are covered by the EU Regulation No 10/2011 that sets out rules on the composition of plastic FCMs.It also establishes a Union List of substances that are permitted for use in the manufacture of plastic or bioplastics FCMs. “Specific Migration Limits” (SML) i.e. the maximum amount of substances allowed to migrate to food, are safe limit of exposure, established by EFSA[2] on the basis of toxicity data of each specific substance used in

[1] Zimmermann, L., Dombrowski, A., Völker, C., & Wagner, M. (2020). Are bioplastics and plant-based materials safer than conventional plastics? In vitro toxicity and chemical composition. Environment international, 145, 106066. https://doi.org/10.1016/j.envint.2020.106066
[2] European FoodSafety Authority

(bio)plastic FCM. Within EU, it is possible to place on the market FCM articles made in (bio)plastic, only if they are made with raw materials indicated in the positive list of EU Regulation No 10/2011 and meet the substance specific migration requirements set by EFSA.
Detailed migration testing rules using “simulants” are defined by the European Regulation and are selected based on scientific and rigorous rational. The migration testing is done under standardised time/temperature conditions, representative for a certain food use, and covers the maximum shelf life of packed food.

However, in order to demonstrate their thesis, the authors followed a different test approach. They treated a very high amount of each material (3 g) with 20 ml of methanol for one hour under sonication. Then, they applied a set of bioassays showing different patterns and levels of toxicity. It is worth to mention that the (bio)plasticcan swollen under those conditions, which obviously do not represent the real situation of exposure.

The rationale behind the tests selection by the authors is not properly explained in the publication. The first toxicity test was performed according to guideline ISO 11348-3, which is usually applied to check the quality of the water and the toxicity of water pollutant towards a bacterium *A.fischeri*. Thus, it is our opinion that this test might be interesting for environmental toxicity screening but it is not adequate to assess human toxicity of FCM.
The second toxicity test was focused on oxidative stress and cytotoxicity, which is not a relevant end point: cytotoxicity is neither considered relevant in the ecotoxicology evaluation nor in EFSA evaluations of food, food additive or FCM.
The third test is an in vitro recognition test with human estrogenic receptors. As several OECD guidelines are available for this kind of study, the decision of the authors to follow other protocols is unclear. Furthermore, the article does not take into account the EFSA-ECHA guidelines on endocrine disruptors, which indicate that the in vitro test with estrogenic receptors cannot be considered conclusive in the evaluation of substances suspected of having hormonal activity.

The most important gap of the article is that it fails to underline the difference between risk and hazard.

The final result was that 67% of bio-based/biodegradable samples showed in vitro toxicity, exactly the same percentage found in fossil-based plastics in a previous study. Thus, the bioplastics are as “toxic” as the conventional ones. We are now looking forward to seeing the outcome of similar studies using other types of packaging, for the sake of completeness, because we expect many other packaging

materials and even natural substances could display a comparable toxic effect under the chosen test conditions.

It is worth to highlight that most of the tested products and materials were FCM, i.e. compliant with the EU laws.
It is now our turn to ask a question: are the authors thinking to propose this scheme to the EFSA? If the authors are suggesting this approach as a better means to determine toxicity of FCM, then this approach should be standardised and validated. In particular, the link between this complex set of testing and the risk to consumers under real life conditions must be established.

To conclude, this is a research project whose scope was to set up screening tests. As a matter of fact, the methodology is preliminary because we still ignore what is the response of natural substances and of other packaging (whether bio-based or fossil-based, plastic-based or cellulose-based etc.), and we ignore what is the link between the toxicity detected at laboratory level and the effective risk posed to the consumers. Thus, the project is in its initial stages. Therefore, it is surprising that the article speciously blames a class of innovative materials for claims that nobody claimed, based on a preliminary not validated testing scheme.