Bad in food but fine in health products?

● Bisphenol A and titanium dioxide: the European Medicines Agency (EMA) disputes the need to remove these substances from health products, yet it is acknowledged that their presence in food is harmful.

Bisphenol A is mainly used to manufacture polycarbonates and epoxy resins, which are present in many food containers and food packaging materials. Food is considered to be the main source of exposure to bisphenol A in the general population (1).

In 2023, the European Food Safety Authority (EFSA) concluded that "*bisphenol A in food is a health risk*" (2,3). Its scientists analysed over 800 studies published since 2013, and determined that this endocrine disruptor has potentially harmful effects on the immune system, metabolism, reproduction and development (1,2). As a result, the EFSA has lowered by a factor of 20 000 the "tolerable" daily intake of bisphenol A, i.e. "*the amount that can be ingested daily over a lifetime without presenting an appreciable health risk*" (2).

The EMA has questioned the strength of the evidence analysed by the EFSA for bisphenol A, a substance used in various stages of the manufacturing and packaging of drugs and medical devices (4). It will be up to the European Commission and European Union member states to decide whether or not to take restrictive measures (2).

Titanium dioxide nanoparticles, used as a colouring and opacifying agent, are genotoxic, carcinogenic and mutagenic in vitro and in animals (5). Following the publication of an opinion by the EFSA, it has been banned from use in food in France since 2020, and in the European Union since 2022 (6,7).

In 2021, the EMA stressed that a blanket ban on titanium dioxide would create a risk of drug shortages (7). Based on input from pharmaceutical companies, it concluded that the industry would need "*a transition period of 10 years or even longer*" (8).

The European Commission is waiting for an updated EMA assessment, expected in 2024, before deciding whether or not to ban titanium dioxide from health products (7).

This is a situation where patients' interests conflict with industry interests. How can these toxic substances be limited or even banned in food, but still authorised in health products? The EMA must persuade pharmaceutical companies to find better alternatives as soon as possible.

► Translated from *Rev Prescrire* January 2024 Volume 44 N° 483 • Page 60

Selected references from Prescrire's literature search

1- Prescrire Rédaction "Le bisphénol A imprègne toute la population" *Rev Prescrire* 2013; **33** (354): 294-300.

2- EFSA "Bisphenol A in food is a health risk" 19 April 2023. www.efsa.europa.eu accessed 21 September 2023: 6 pages.

3- EFSA "Re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs" *EFSA journal* 2023; **21** (4): 392 pages.

4- EFSA-EMA "Report on divergent opinion between EFSA and EMA on bisphenol-A_final adopted" 2023: 9 pages.

5- Prescrire Editorial Staff "Titanium dioxide: is it carcinogenic?" *Prescrire Int* 2021; **30** (230): 243.

6- Institut national de recherche pour l'agriculture, l'alimentation et l'environnement "Dioxyde de titane: la bouche, première voie de passage du E171 dans le sang" 17 May 2023. www.inrae.fr accessed 2 October 2023: 2 pages.

7- "Commission Regulation (EU) 2022/63 of 14 January 2022 amending Annexes (...) as regards the food additive titanium dioxide (E 171)": 6 pages.

8- EMA "Final feedback from European Medicine Agency (EMA) to the EU Commission request to evaluate the impact of the removal of titanium dioxide from the list of authorised food additives on medicinal products" 8 September 2021: 11 pages.