

Summary

The FDA, the agency in charge of food safety, has proposed new rules governing food additives. Some of the proposed rules are reasonable, but one of them could pose risks by allowing very small doses of toxic chemicals to be used in foods.

According to the [Guardian](#) news site, a proposed new FDA [regulation](#) will “expand a controversial loophole to allow some of the world’s most toxic chemicals to be added directly to food without a safety review.” The proposed regulation does two other, seemingly reasonable, things along with the one that raises real concerns. The worrisome part of the proposal may have been shoehorned into an otherwise innocuous proposed rule, with very little explanation of the added provision.

Perhaps the scanty explanation was an oversight or perhaps the Administration is once again playing fast and loose with public health.

The first (reasonable seeming) change adds a notice requirement. It requires companies to notify FDA when they are using an exemption from FDA review called GRAS (or Generally Regarded as Safe.). According to the FDA, there may be around a thousand substances that companies are classifying as GRAS, but FDA doesn’t really know what they are or who is using them. Requiring notice would let FDA monitor the situation and intervene when appropriate. This seems like a good idea, although it’s a tepid step given RFK Jr.’s pledge of a crackdown on GRAS additives back when he was a presidential candidate.

The other two changes relate to the TOR, which stands for Threshold of Regulation.

Currently, FDA considers any amount of a substance below 0.5 parts per billion to be harmless. (There’s a different rule for carcinogens, which we don’t need to get into.) FDA proposes to change the threshold to an estimated daily intake of 0.025 micrograms (25 nanograms) per kilogram body weight per day. Even if a substance is below this level, FDA could still object to the exemption if it has other health concerns.

FDA seems to think that the old “ppb” and the new “microgram” standards would be equivalent for an average member of the population. FDA argues that restating the standard this way makes it more responsive to differences between subgroups.

That seems reasonable enough on its face, assuming they’ve done the numbers right. There could be problems with these first two proposals that an expert in food regulation would catch, but nothing jumps out as unreasonable.

That brings us to the controversial part of the proposal. Currently, the TOR standard applies only to substances that get on the food from packaging or processing machinery. If a substance's concentration is below the threshold amount, it's exempt from regulation. For instance, a dye called C.I. Solvent Blue 36 can be used "up to 0.011 % by weight in foamed polystyrene articles used in contact with all types of food under refrigerated temperatures."

FDA proposes to expand the TOR exemption to include food additives as well as things that just come into contact with foods. The assumption seems to be that this is only reasonable — why should it matter exactly how the substance gets into the food? — and that the threshold is low enough that there's no plausible risk to consumers.

The FDA provides no evidence that the numerical level of the threshold is right or that expanding the exemption to cover food additives presents no risks. In terms of the numerical level, the Guardian quotes experts who think that the threshold FDA is contemplating is much too high for some substances. In that case, rather than being extended to new uses of chemicals, the threshold should be lowered for at least some types of chemicals other than carcinogens. FDA says nothing to defend the existing threshold.

FDA also doesn't explain why the TOR process it had previously used only for incidental exposures such as substances in packaging or why dramatically expanding the use of the exemption to all food contents is unproblematic. If we go from about 150 exemptions to 1500, for instance, the cumulative effect of the resulting toxic cocktail could have a significant health impact even though no individual toxic exemption poses a significant risk by itself.

There's also a major procedural problem with the process that FDA proposes. Under FDA's proposed rule, a manufacturer would submit a request for an exemption for a proposed use to FDA. If approved, FDA will post a notice that this use of the substance has been exempted. (Here is a [current list of exemptions](#).) Others manufacturers can make similar use of the substance without adding a new request. That makes the exemption a rule, which should be accompanied by notice to the public and an opportunity to comment. Instead, the public will only have access to the information supporting the exemption through a FOIA request, which takes forever, and the information will be redacted to eliminate trade secrets, an elastic category.

Fortunately, the FDA's current proposal itself is still going through notice and comment. One of the benefits of notice and comment rulemaking is that the opponents will get a chance to critique the study and force the FDA to come up with a better analysis. If FDA's revised analysis raises important new issues, FDA may have to start the process all over to give opponents a chance to respond to the new arguments or data introduced by FDA.

If nothing else, we should find out a lot more about the merits of the proposal than FDA has told us so far. In an Administration that has made a point of disdaining expertise and data, there is no reason to give FDA the benefit of the doubt. If anything, we should presume the opposite.