...our research found the FDA regulatory system is plagued with systemic problems that prevent the agency from ensuring their use is safe

– Pew Report

Food contact spotlight

Critique of US food contact programme seen as unfairly harsh
Experts with decades of experience challenge the complaints and remedies proposed for notifications of substances used in packaging

The Pew Charitable Trusts, a non-profit public advocacy organisation supported by a family inheritance from the petroleum industry, has been supporting an in-depth critique of regulatory programmes at the US Food and Drug Administration (FDA) for food additives, including food contact materials. The probe has been so relentless that the FDA felt obliged to assign a staff person at the agency to deal with Pew’s inquiries.

Pew’s investigation has finished up after three years (see Food Contact World 7.5). The ramifications of the Pew report may be far-reaching. The Natural Resources Defence Council advocacy group has taken the Pew researchers aboard to carry on the legislative fight to reform FDA’s rules and procedures.

To set the stage for the debates that are likely to come, Food Contact World asked two experts to provide their opinions on key assertions related to food contact matters in the final Pew report, Fixing the Oversight of Chemicals Added to Our Food.

Richard Kraska is COO and co-founder of Gras Associates, a technical consulting firm for the food and allied industries on matters related to the review of food ingredients and chemicals that may be considered ‘generally recognised as safe’ (Gras) as defined by law and in the FDA regulations. He began his career in 1981 with the federal agency in food additives and Gras review. He then spent 22 years on regulatory matters with three US chemical companies.

Joan Sylvain Baughan is a partner in the Washington, DC, office of Keller and Heckman, which she joined in 1991. She practices food and drug law focusing on the FDA and comparable international regulation of food contact materials. She has served as general counsel for the Society of the Plastics Industry committee for food, drug and cosmetics packaging materials.

Pew Assertion #1: ‘The FDA uses outdated science to evaluate additive safety. It relies on a process that does not ensure independent scientific input and is often not transparent, particularly for food contact substances.’
RK: ‘All existing regulatory systems for chemicals should be subject to periodic improvement. Increasing the transparency of these processes is important to all stakeholders. However, all science-based risk decisions basically come down to judgment of scientific experts.

The scientific process the FDA uses in its review of Gras notifications (GRNs) and food contact notifications (FCNs) is not outdated, and is basically the same methodology used by the Joint FAO/World Health Organisation (WHO) Expert Committee on Food Additives (Jecfa) [an international expert scientific committee of the UN] and the European Food Safety Authority (EfSA). Jecfa comprises the world’s experts on the subject of food additive safety. Any debate on improvements of the science should be conducted in a scientific forum such as the Society of Toxicology or brought to a body like Jecfa.

The transparency Pew desires does not affect the scientific method, but it does reflect on the risk management principles used to determine whether a certain exposure level is safe. That is a legitimate subject for public debate.

An increase in transparency in the FCN programme would demonstrate that the FDA’s review is rigorous, and the review methodology is highly conservative and errs on the side of consumer safety. Increased transparency would demonstrate the fact that most new food contact substance approvals involve uses with very low potential for consumer exposure. It should be noted that the FDA has implemented advancements in scientific principles with the threshold of regulation concept that is based on threshold of toxicological concern principles, which have wide support in the scientific community.’

JSB: ‘The claim that the FDA uses outdated science to evaluate food additive safety is unfounded, and is supported in the Pew report only by citations to other publications that have been authored by the same officers of the Pew Food Additive Project. The FDA has led the world in developing scientifically valid approaches to food additive safety, both within the agency, and through collaboration with other countries and international organisations such as FAO and WHO.

It appears that Pew’s justification for stating that the FDA relies on a process that does not ensure independent scientific input is that the vast majority of safety and exposure data on food additives is generated by industry. This, of course, is true because
it is the additive manufacturers who must develop the data upon which to make safety determinations about the products they produce. The manufacturers are developing the data and requesting the clearances where appropriate. Pew’s statement that financial conflicts of interest in the FDA’s Gras decisions are “ubiquitous” is unsupported and dismissive of the agency’s integrity.

Further, the statement that the FDA relies on a process that is not transparent, “particularly for food contact substances,” is simply not true. All of the safety data supporting an FCN and the FDA’s evaluation of the same is available to the public pursuant to the Freedom of Information Act. This is not true in the EU, for example, where copies of toxicity studies that support regulatory clearances often are considered to be confidential business information and not releasable to the public. Entities wishing to obtain copies of the toxicity studies that the EU regulatory authorities have relied upon in making safety determinations often must independently work out data compensation agreements with the submitting companies.

Pew Assertion #2: ‘The Gras notification and the food contact substance notification programme should be limited to changes in existing uses or to additional uses only after the FDA has approved the chemical’s use in food.’

RK: ‘The FCN and GRN programmes are highly efficient improvements over the petition process and limitations on the scope of these programmes are not desirable. Both programmes have increased the transparency of FDA reviews on new food contact substances and food ingredients. It is much easier to explain these regulatory programmes to clients, especially foreign companies, than the old system of adding chemicals to the code of federal regulations. I would also suggest that many FCNs are for chemicals that are safer or more environmentally responsible than the chemicals that are currently allowed. Many FCNs are submitted to provide substances that are more biodegradable, or are used in water-based systems rather than solvent-based systems. Curtailing these programmes would tie the hands of industry in making progress in the areas of worker safety, waste generation, reduction of volatile organic compounds, and energy usage.’

JSB: ‘It is hard to imagine what benefit this would achieve. Is Pew suggesting that the FDA doesn’t really review or evaluate GRNs or FCNs?’

Pew Assertion #3: ‘To ensure that the notification programmes are transparent and credible, Congress should allow the FDA to revise the food contact substance notification programme so it is more transparent. The notices, with confidential business information removed, should be publicly available on its website before the agency takes final action.’

RK: ‘An increase in the information available on the FDA’s website on FCNs to the same extent as for GRNs is desirable. It would benefit both the industry and the public.

There have been small but important changes in the FDA review methodology, such as the use of market share in estimating potential exposure. This information is not necessarily available unless a Freedom of Information (FoI) Act request is submitted for a particular FCN. This change has not been reflected in the FDA guidelines.
'While some may criticise this change, it is based on common sense and demonstrates that new food contact substances have low potential for risk due to the low level of possible consumer exposure. Pew’s premise would seem to assume that new chemicals introduced through the FCN process are more hazardous than older listed chemicals. However, many of the older chemicals were listed 50 years ago with a minimum of FDA review. New chemicals allow for the introduction of new technology and replacement of older chemicals, which are undesirable from an environmental or worker safety standpoint.'

JSB: ‘Here, Pew seems to be confusing transparency with timing. Again, copies of the safety data and evaluations supporting FCNs are publicly available through FoI. This comment in the Pew report appears not to reflect an actual problem with obtaining the information needed to understand and explain the FDA’s evaluations of the safety of food contact substances, but rather a desire to direct and oversee them.’