Published on *The National Law Review* https://natlawreview.com

IARC Releases Its Priority Evaluation List for 2025-2029

Article By:

John Kalas

Joseph E. Fornadel, III

Matthew Abney

The International Agency for Research on Cancer (IARC) released its 2025-2029 Priority List for evaluation in April of this year, s*ee* Advisory Group Recommendations on Priorities for the IARC Monographs, The Lancet Oncology (April 2024).(1) Manufacturers of all stripes — and their inside and outside counsel — should be aware of the list and begin preparing for eventual evaluations by IARC Working Groups.

What is IARC?

The IARC is a branch of the World Health Organization ("WHO"). It is based in Lyon, France. Mandated by the WHO to investigate potential causes of cancer, IARC conducts hazard evaluations of suspected carcinogens multiple times a year. The results of these evaluations are published in IARC "Monographs" — lengthy summary publications that discuss the existing literature and then apply a cancer classification based upon the Monograph Working Group evaluation. Under current IARC guidelines, it is impossible to classify any evaluated substance as "not carcinogenic" — the best the guidelines allow is "insufficient evidence to deem carcinogenic."

See IARC Update Frustrates Industry and NGOs, *Chemical Watch*, May 2, 2019 (discussing removal of "probably not carcinogenic to humans" classification from IARC preamble).(2) Additionally, IARC Monograph Working Groups — with few exceptions — are only allowed to consider as part of their review published data in the peer-reviewed literature regarding substances or exposures they evaluate. In the case of regulated substances, where many safety studies are submitted to regulators but are not placed in the peer-reviewed literature, this can create a situation where IARC Working Groups only review a subset of the available data on a given compound or exposure, potentially leading to erroneous conclusions based on incomplete data sets.

IARC evaluations have been at issue in litigation for decades, starting first with the earlier iterations of asbestos cases in the 1980s and 1990s. In recent years, IARC evaluations of the chemical aspartame (found in Diet Coke) and perfluorinated chemicals have garnered widespread attention. *See*, e.g., Does Aspartame Cause Cancer? It's Complicated, *Chemical and Engineering*

News (April 28, 2024) (discussing aspartame classification and regulatory response).(3) Earlier IARC evaluations of the active ingredient in the pesticide Roundup (glyphosate), the active ingredient in the pharmaceutical drug Actos (pioglitazone), polychlorinated biphenyls (PCBs), and benzene either spurred or rekindled personal injury litigation surrounding those compounds.

In addition to personal injury litigation, an IARC classification of "carcinogenic" (Group 1) or "probably carcinogenic" (Group 2a) results in automatic listing as carcinogenic under California's Proposition 65 law. Under Proposition 65, bounties are available to private citizens or organizations who bring lawsuits claiming products contain levels of listed carcinogens that exceed the state's safe harbor level. These Proposition 65 lawsuits have been brought alleging undisclosed carcinogens in products like coffee and french fries. See The Secretive Non-Profit Gaming California's Health Laws, *The Outline* (June 18, 2018) (discussing Proposition 65 lawsuits).(4)

Courts have expressed a healthy skepticism of IARC classifications. *See Nat'l Assoc. of Wheat Growers v. Bonta*, 85 F.4th 1263, 1278 (9th Cir. 2023) ("IARC stands essentially alone in its determination that glyphosate is probably carcinogenic to humans, while the US Environmental Protection Agency, California Environmental Protection Agency's Office of Environmental Health Hazard Assessment, and regulators from around the world conclude that it is not."). Despite that skepticism, IARC classifications continue to spur litigation time and time again, and most courts still allow the findings of IARC Working Groups to provide a basis for claims against corporate defendants in a wide variety of cases.

The 2025-2029 Priority List

IARC's Priority List for 2025-2029 lists dozens of chemicals, pharmaceuticals, consumer products, and other exposures slated for IARC Working Group review over the next five years. In order to be placed on the IARC Priority List for review, a substance must be nominated for consideration by IARC. Then, the Advisory Group for the Priority List reviews the nominations and chemicals in question and suggests priorities for review over the coming years after reviewing evidence available on the compounds and exposures in question. Members of the Advisory Group for 2025-2029 included both academic and governmental scientists.(5)

The Advisory Group recommended dozens of substances for "high priority" review — their highest level of recommendation. Some of the more notable substances nominated as high priority for review between 2025 — 2029 include:(6)

Hair Straightening Products	Not Previously Evaluated
Hair Coloring Products	Previously Classified as "Not Classifiable"
GLP-1 analogs (e.g., Ozempic, Wegovy)	Not Previously Evaluated
JK inhibitors (e.g., Xeljanz, Rinvoq)	Not Previously Evaluated
Assorted Pesticides (e.g., Chlorpyrifos, Alachlor, Pyrethrins, Atrazine, Carba[1]ryl, etc.	Mix of Not Previously Evaluated and Previously Classified
Electronic Nicotine Delivery Systems	Not Previously Evaluated
Acetaminophen (e.g., Tylenol	Previously Classified as "Not Classifiable"

Textile Manufacturing Work	Previously Classified as “Possibly Carcinogenic”
Progesterone-only contraceptives	Previously Classified as “Possibly Carcinogenic”
Asbsestos	Previously classified as “carcinogenic” but now with evidence at new sites
Hormone-Replacement Therapy	Previously classified as “carcinogenic” but now with evidence at new sites

Many of these substances or exposures have been the subject of previous personal injury or Proposition 65 litigation, but an upgrade in classification or findings at new sites may spur additional litigation.

Unfortunately, IARC’s conflict-of-interest policy has been applied inconsistently to the makeup of their working groups in the past. For instance, IARC has previously allowed expert witnesses in litigation for plaintiffs to serve on working groups examining exposures about which they’re testifying while excluding from participation individuals with ties to companies producing the exposures. *See, e.g., Newman v. Motorola*, 78 F. App’x 292, 293-94 (4th Cir. 2003) (discussing expert testimony of Lennart Hardell – a later participant in IARC Working Group on RF Electromagnetic Fields) *and* https://www.reuters.com/article/us-health-who-iarcspecial-report-idUSKCN0XF0RF (discussing exclusion from same working group of Anders Ahlbom). More recently, a toxicologist from UC-Berkeley named Luoping Zhang was permitted to serve on an IARC Working Group regarding benzene despite the fact she had received research funding from groups managed and funded by plaintiff attorneys bringing benzene lawsuits. No conflict was disclosed. *See* IARC Monograph 120 Working Group Members (found at IARC Publications Website - Benzene); Fromowitz, et al., *Bone Marrow Genotoxicity of 2,5-Dimethylfuran, a Green Biofuel Candidate*, 53 Env. Mol. Mutag. 488 (2012) (disclosing grant funding for article from Council for Education and Research on Toxics (“CERT”)); The Secretive Non-Profit Gaming California’s Health Laws | The Outline (discussing leadership of Raphael Metzger pertaining to CERT); Schachtman Law » THE COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS (discussing Metzger’s benzene lawsuits and Zhang’s work on amicus briefs for CERT).

Given IARC’s disparate treatment of conflicts of interest in the past, it is possible that future working groups will lack a balance of viewpoints as well, leading to classifications that do not reflect scientific consensus. Over the past decade, IARC classifications for a multitude of chemicals have been criticized by regulatory authorities as out-of-step with the scientific data. See Aspartame and Other Sweeteners in Food | FDA (discussing FDA disagreement with IARC as to aspartame); *Glyphosate | US EPA* (discussing EPA disagreement with IARC as to glyphosate).

How to Prepare for a Monograph Review

Companies, trade groups, and other interested parties can prepare for IARC Monograph reviews in a few ways:

- First, closely monitor the timing and makeup of IARC Working Groups. An announcement for

participant nominations and a preliminary list of participants will be released in the months prior to the Working Group meeting. Nominating impartial researchers who evaluate the weight-of-the-evidence and closely examining the publications and affiliations of named participants for signs of bias may provide advance warning of an unbalanced review that is forthcoming and also may provide some opportunity to protest the inclusion of any predisposed participants.

- Second, consider what data may not be available, but could be published in the peer-reviewed literature without negatively affecting business operations. The more data that can be made available in the literature, the more data IARC — under its guidelines — will be able to consider in its review. This is especially important in areas where little data supportive of safety may be publicly available like mechanistic data. Often, much of the mechanistic data in the published literature is of low quality due to design issues (non-OECD, product of non-GLP lab, etc.) but if it is the only data a Working Group has for use, it will be used. Greater availability of data supportive of product safety may help scientists at IARC avoid mistakes in classification, though even then, IARC may disregard certain information. *See Tarone, Conflicts of interest, bias, and the IARC Monographs Program*, 98 Regul. Toxicol. Pharmacol. A1-A4 (2018).
- Third, send observer(s) to the Working Group meeting in Lyon, France. Though individuals with IARC-designated conflicts of interest (i.e., consulting with industry) may not participate in working groups, they may observe much of the meeting. Sending observers may help interested parties gain valuable insight into the thought process of the Working Group and the evidence they found most compelling to their ultimate classification.
- Fourth, start educating the public and relevant regulatory and political bodies about what goes into an IARC classification. Specifically, the public and relevant bodies should be aware that IARC often relies upon incomplete data as the policies under which working groups operate do not allow for the review of data not in the peer-reviewed literature or publicly released by regulatory agencies. Thus, in many cases, IARC Working Groups do not consider many of the regulatory guideline studies necessary for product registration in the US and elsewhere. Additionally, interested parties should be aware than an IARC evaluation is a “closed” analysis — no peer review or public comment is permitted and no transcript is kept of the meeting or its deliberations. Shrouded in secrecy, exposing flaws in IARC’s process can be difficult after the fact. Finally, the public and relevant bodies should be informed that an IARC evaluation is a hazard assessment — in other words, it is a determination that a substance might be carcinogenic at some dose, but it does not address whether the dose people are exposed to in their daily lives could cause cancer.
- Finally, prepare for litigation — both of the Proposition 65 and personal injury variety. Involve in-house and potentially outside counsel in developing a strategy to deal with regulatory fallout in addition to potential litigation and customer concerns about a change in classification. During this preparation, be aware that many of the efforts outlined in the four bullets above may become subject to discovery.

By virtue of its association with the United Nations and by the participation of many individuals associated with impressive institutions, IARC Working Group classifications may be held in high regard by jurors and/or members of the general public. Early planning and a concerted, concentrated effort led by interested parties is key to ensuring sound science is employed in evaluations by IARC and other agencies reacting to IARC’s evaluation. Industries and interested parties associated with substances on the Priority List for 2025-2029 should begin their preparations now.

---

(1) Advisory Group recommendations on priorities for the IARC Monographs - The Lancet Oncology
2 https://chemicalwatch.com/77053/iarc-update-frustrates-industry-and-ngos

(2) https://chemicalwatch.com/77053/iarc-update-frustrates-industry-and-ngos

(3) Does aspartame cause cancer? It’s complicated (acs.org)

(4) The secretive non-profit gaming California’s health laws | The Outline

(5) https://monographs.iarc.fr/wp-content/uploads/2019/02/AGP-ListofParticipants.pdf

(6) A full list of the Priority List can be found here: Advisory Group recommendations on priorities for the IARC Monographs - The Lancet Oncology

National Law Review, Volume XIV, Number 256

Source URL:https://natlawreview.com/article/iarc-releases-its-priority-evaluation-list-2025-2029