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U.S. District Court in DC Breaks New Ground for TSCA Transparency

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The U.S. District Court for the District of Columbia recently found, in what it described as a "question of first impression," that Section 5(b)(3) of the Toxic Substances Control Act (TSCA), a provision requiring public disclosure of information on the receipt of new TSCA Section 5 filings and health and safety data, was a "freestanding right to information" obligation and independent of a TSCA regulatory function. This court, in its August 20 opinion, reiterated the position that public right-to-know about chemicals in commerce is a central function of TSCA.

The case, *Environmental Defense Fund (EDF) et al. v. Michael S. Regan et al.*, Civil Action No. 20-762 (LLA), arose when the plaintiffs, five environmental organizations, sued the U.S. Environmental Protection Agency (EPA or Agency) and EPA Administrator Michael S. Regan to enforce the transparency and disclosure requirements of TSCA, specifically those related to TSCA Section 5 new chemical submissions. The statute provided strict timelines for the public identification, by the Agency, of TSCA new chemical submissions and the receipt of new chemicals test data. The Agency was failing to meet these deadlines.

EDF and others had pressed EPA on the statutory requirements regarding transparency and production of Section 5 materials, and following months of discussions – and the Agency's production of some, but not all, the requested materials – EDF et al. filed suit per the Administrative Procedures Act (APA) and TSCA Section 20 (citizens' civil actions). The plaintiffs asserted that the public was granted rights under the statute, including timely access to information, and that the Agency by its actions and inactions denied these rights.

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Much of the opinion deals with the case's pending procedural issues, and the court made a ruling granting the plaintiffs' request for the generation by the Agency of a full administrative record and denying EPA's motion for judgment. The court did take the opportunity to make substantive comments about transparency and disclosure requirements of TSCA Section 5.

A notable point the court made was that TSCA Section 5(b)(3) was a "freestanding" general disclosure provision, and that the EPA obligation to make the information "available for examination by interested persons" is unrelated to any TSCA specific chemical management activity. This is validation for public advocacy groups' oft-repeated position that TSCA is a "right-to-know" statute.

Nevertheless, the court affirmed that TSCA Section 14's rules for confidential business information (CBI) protection apply to disclosing premanufacture notice (PMN) information. PMN submitters can assert CBI protection for the information in these files, and certain information has to be substantiated at the time the claim is made. When making PMN information public, Section 14(c)(B) of TSCA requires that EPA take "reasonable measures to protect the confidentiality of the information" claimed as CBI in the submissions. The Agency must affirmatively find that information claimed CBI is not required to be disclosed or otherwise made available to the public under any other federal law. EPA also must have a reasonable basis to conclude that disclosure is "likely to cause substantial harm to the competitive position of the [applicant]." The court noted that while certain types of documents, such as health and safety studies, cannot be entirely withheld from disclosure under the CBI exemption of the Freedom of Information Act (FOIA), other FOIA exemptions might apply to the situation.

Importantly, the court found that, while there was a time deadline for the posting of a notice of the receipt of TSCA Section 5 new chemical filings and receipt of health and safety data, it did not find that there was a mandated period for the public posting of the material. Also, the court noted that there was no strict timing deadline for the posting of notices of the receipt of test marketing exemptions (TMEs).

The court's opinion consistently closely hues to the language of the statutory text: Where the provision required notice to be provided within five days, the court upheld the obligation. Where the TSCA provision does not contain a time provision, the court did not create one. So, for example, concerning the Agency's statutory obligation to post a notice of receipt of a TME, given that there was no timeline for the posting, the court ruled "that the EPA has a nondiscretionary duty to publish notice of TME applications within forty-five days of receiving said applications" – the 45 days being the time frame by which the Agency must decide on the application. The 45-day deadline for posting notice of the receipt was necessary to provide some opportunity, however short, for public participation in the decision-making process.

In conclusion, the significance of the opinion is the court confirmation that there is a distinct transparency element to the new chemicals review process, the parameters of which are defined by the specific statutory text.

A predictable consequence of the court's ruling is that there will be more CBI reviews related to Section 5 filings. Not only will industry be dealing with the now predictable TSCA Section 14(g) reviews, but it is most likely there will be more publicly triggered TSCA Section 14(f) reviews, which are more comprehensive in the context of a FOIA request for materials claimed as CBI. The opinion reminds TSCA practitioners of the importance of developing a well-thought-out approach for the assertion of CBI claims in TSCA filings in general, and TSCA Section 5 submissions in particular. Developing robust substantiations and successfully managing the TSCA Section 14 review process is an area of TSCA that calls for increasing attention and skill.

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