



April 19, 2023

Dr. Michal Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460

Re: EPA Review and Public Comment Process for SNUNs Submitted by Inhance Technologies

Dear Assistant Administrator Freedhoff:

We are writing to request that EPA address significant deficiencies in its request for public comments on the Significant New Use Notices (SNUNs) submitted by Inhance Technologies on the fluorination of plastic containers. We also would like to meet with your staff to discuss the process and timeline for commenting on these SNUNs and the status of EPA's SNUN review.

In the attachment to this letter, we have outlined numerous concerns about EPA's process for Federal Register publication and public comment on recent SNUNs submitted by Inhance Technologies. Because of these deficiencies, PEER, CEH and the public have been prevented from conducting an in-depth review of the SNUNs and developing meaningful comments, as TSCA and EPA procedures require.

For example, we have found 18 SNUNs from Inhance for fluorinating plastic containers in EPA's database, ChemView. However, EPA has only provided public notice and an opportunity for comment on nine SNUNs received on December 30, 2022. No notice and opportunity for comment have been provided on the other nine SNUNs, which were received on March 7-8, 2023, according to ChemView.

In addition, the SNUNs published by EPA are riddled with inconsistencies. For example, in the thousands of pages of attachments, there are numerous numbering and organizational problems. To add to these problems, some of the Attachments to the SNUNs that were once in ChemView are no longer in ChemView without an explanation for why they were removed. Also, large portions of the SNUNs remain redacted, even though they contain health and safety data required to be disclosed by TSCA.

EPA's failure to provide proper public notice on these SNUNs is troubling. The long-chain perfluoroalkyl carboxylate (LCPFAC) substances subject to these SNUNs cause significant adverse health effects and are present in tens of millions of fluorinated containers distributed in

commerce, resulting in exposure by a large segment of the U.S. population. In fact, EPA has just proposed Maximum Contaminant Levels (MCLs) for one of the PFAS being manufactured by Inhance, PFOA. In its Federal Register notice for these proposed MCLs, EPA states, "... there is no dose below which [PFOA] is considered safe."

In view of these public health concerns, it is vital that EPA follow proper public notice and comment procedures and that the public is fully engaged in the SNUN review process. To date, that has not happened. We therefore request that EPA address the problems we have raised in the attachment by including the nine new SNUNs in its next monthly FR notice announcing section 5 submissions and setting a schedule for public comment. In so doing, EPA should align the comment deadlines for the two sets of SNUNs so that commenters can address the interrelated issues they raise in one submission.

The EPA review periods for the 18 SNUNs should similarly be aligned because EPA needs to evaluate them as a package and make one set of risk determinations and risk management decisions. To facilitate an orderly and integrated review process, EPA should ensure that the review periods for all 18 SNUNs end on the same date. EPA has already obtained Inhance's agreement to a 60-day suspension of the review period for the first nine SNUNs, which would result in its termination on May 29, 2023. However, this extended review period is likely insufficient for a thorough review of the nine SNUNs received on March 7 and 8. We therefore request that EPA use its authority under TSCA section 5(c) to extend the review periods for all 18 SNUNs by an additional 90 days. With this extension, the review period for these SNUNs would end in late August.

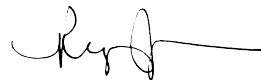
In sum, it is urgent that we meet with your staff to resolve the length of the review period and applicable comment deadlines for the 18 SNUNs. We also need to discuss how EPA can accelerate its CBI reviews of the SNUNs so our groups have access to health and safety data that is necessary for our review of the SNUNs.

Please contact Tim Whitehouse of PEER at twhitehouse@peer.org to arrange a meeting with your staff on these issues as soon as possible.

Sincerely yours,



Timothy Whitehouse
Executive Director
Public Employees for Environmental Responsibility



Regina Jackson
Interim Chief Executive Officer
Center for Environmental Health

cc: Denise Keehner (OPPT)

Mark Hartman (OPPT)

Madison Le (OPPT)

Shari Barash (OPPT)

Susanna Blair (OPPT)

Ryan Schmidt (OPPT)

N. Lindsay Simmons (OECA)

Attachment:

PEER/CEH Chronology of Inhance SNUN Submissions and EPA Actions

Attachment

PEER/CEH Chronology of Inhance SNUN Submissions and EPA Actions

In its Federal Register notice of February 17, 2023,¹ EPA announced the receipt of 12 Significant New Use Notices (SNUNs) on December 30, 2022. Although the submitter identities were listed as confidential business information (CBI), Inhance neglected to redact its name from one of the documents, so it was clear that these nine SNUNs were from Inhance. Since that initial submission in December of 2022, Inhance has unredacted its name. The SNUNs attributed to Inhance (see Figure 1) are designated SN-23-0002 through SN-23-0006, and SN-23-0008 through SN-23-0011. The February 17 FR notice set a comment deadline of March 20, 2023, for these SNUNs.

Figure 1











Case No.	Version	Received date	Manufacturer	Use
SN-23-0002	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0003	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0004	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0005	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0006	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0008	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0009	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0010	2	12/30/2022	CBI	(G) The LCPFACs have no function or application
SN-23-0011	2	12/30/2022	CBI	(G) The LCPFACs have no function or application

¹ <https://www.federalregister.gov/documents/2023/02/17/2023-03362/certain-new-chemicals-receipt-and-status-information-for-january-2023>

As we noted in our letter to Assistant Administrator Freedhoff of March 15, Inhance made several additional submissions to the docket on March 7 and 8, 2023, which we initially believed were amendments to the nine SNUNs received by EPA on December 30, 2022. We therefore requested a 60-day extension of the comment period because of the lack of adequate time to review these new submissions.

On March 20, 2023, at the request of PEER and CEH, a new FR notice extended the comment period for an additional 60 days.² However, no new SNUNs were listed in this FR notice. Indeed, when we searched for all the SNUNs submitted to EPA for FY 2023 on ChemView, we only found the 12 listed in the February 17 notice. (See Figure 2).

Figure 2

Structure	Chemical Name/ Chemical Identifier
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,17,17,18,18,18-Pentatriacontafluorooctadecanoic acid 16517-11-6
	Undecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heneicosafuoro- 2058-94-8
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,12-tricosafuorododecanoic acid 307-55-1
	Perfluorooctanoic acid 335-67-1
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-Nonadecafluorodecanoic acid 335-76-2
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-Heptadecafluorononanoic acid 375-95-1
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,14-Heptacosafuorotetradecanoic acid 376-06-7
	(3-Methyl-5-prop-2-enyloxypentyl) prop-2-enoate 64194-22-5
	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,14,14,15,15,16,16,16-Hentriacontafluorohexadecanoic acid 67905-19-5
	Tridecanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,12,12,13,13,13-pentacosafuoro- 72629-11-8

Showing 1 to 10 of 12 entries

Therefore, the only SNUNs that have been noticed in the FR are the following: SN-23-0002, SN-23-0003, SN-23-0004, SN-23-0005, SN-23-0006, SN-23-0008, SN-23-0009, SN-23-0010, and SN-23-0011.

² <https://www.federalregister.gov/documents/2023/03/20/2023-05760/certain-new-chemicals-receipt-and-status-information-for-january-2023-extension-of-comment-period>

However, we recently obtained the attached copy of a March 17, 2023 letter to EPA from an Inhance consultant, Xcel, entitled “Suspension of Review Period for SN-23-0002 through SN-23-0021,” identifying a total of 18 SNUNs filed by the company. The letter lists the 18 SNUNs in the following table (see Figure 3).

Figure 3

Species #	Compound Abbreviation	CAS Number	Fuel Uses	Consolidated groupings	Container Uses
1	PFOA	335-67-1	SN-23-0002	Fuel SNUNs 1	Container SNUNs 1
2	PFNA	375-95-1	SN-23-0003		
3	PFDA	335-76-2	SN-23-0004		
4	PFuDA	2058-94-8	SN-23-0005		
5	PFDoA	307-55-1	SN-23-0006		
6	PFtrDA	72629-94-8	SN-23-0013	Fuel SNUNs 2	Container SNUNs 2
7	PFteDA	376-06-7	SN-23-0014		
8	PFHxDA	67905-19-5	SN-23-0015		
9	PFODA	16517-11-6	SN-23-0016		

The SNUNs labeled SN-23-0013 through SN-23-2021 would appear to be the nine submissions that Inhance made on March 7-8, 2023. Since these submissions received new identifiers, they appear to be new SNUNs rather than amendments to the earlier submissions. As new notices, these SNUNs should be, but have not been, noticed in the Federal Register and there is at present no comment deadline. It also appears that Inhance has filed separate SNUNs for “fuel uses” and “container uses” even though both groups of SNUNs relate to the same nine LCPFACs.

Since they are new submissions, the 90-day review period should have started on March 7-8, 2023 and concluded in early June. However, Inhance’s March 17, 2023, letter incorrectly assumes that the review period for all 18 SNUNs began on December 30, 2022, and with the 60-day suspension requested by EPA, would end on May 29. This is plainly not the case for SN-23-0013 through SN-23-2021 since the review period did not begin until March 7-8. Assuming the 60-day suspension applies to these SNUNs, their review period would end in early August.

Adding to the confusion, the way in which EPA organized the SNUNs in ChemView makes it impossible for the public to comment. For example, SN-23-0011 is for Inhance's manufacture of PFODA (CAS # 16517-11-6). Half the documents in ChemView are listed under SN-23-0011, and the other half are listed under SN-23-0016 (all for the same PFAS, PFODA). To reiterate, SN-23-0016 is not in the FR.

Moreover, EPA has posted yet another table on its website which states there are 16 SNUNs that are being reviewed from fiscal year 2023³ (see Figure 4).

Figure 4

Case Number	Received Date	Interim Status
SN-23-0001	11/03/2022	Scoping Meeting Occurred
SN-23-0002	12/30/2022	
SN-23-0003	12/30/2022	
SN-23-0004	12/30/2022	
SN-23-0005	12/30/2022	
SN-23-0006	12/30/2022	
SN-23-0007	01/09/2023	
SN-23-0008	12/30/2022	
SN-23-0009	12/30/2022	
SN-23-0010	12/30/2022	
SN-23-0011	12/30/2022	
SN-23-0012	01/04/2023	
SN-23-0013	03/07/2023	
SN-23-0014	03/07/2023	
SN-23-0015	03/07/2023	
SN-23-0016	03/07/2023	

Showing 1 to 16 of 16 entries (filtered from 2,278 total entries)

This table lists some but not all the Inhance SNUNs filed on March 7-8.

Finally, some attachments that were present in the December SNUN filings have disappeared (e.g., an Illinois wastewater permit), and other attachments are identical but have different attachment numbers (e.g., in December, Attachment 1 was "Statement of the Presence of SNUN Substances in Fluorinated HDPE Containers" but in the March filing, it is now Attachment 3).

³ <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and>

Conclusion

It does not appear that EPA has properly noticed SNUNs 23-0013 through 23-0021. Moreover, it is unclear which attachments apply to which SNUNs. EPA must publish all the SNUNs in the FR and renumber all attachments so that it is clear which supporting documents pertain to which SNUNs. The confusion regarding these SNUNs is resulting in a total lack of transparency and a failure of EPA to seek robust comments from the public.