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Environmental Defense Fund's Comments on ChAMP:
EPA's Recent Commitments and Possible New Initiatives for Existing Chemicals

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These comments discuss Environmental Defense Fund's views as to what EPA's priorities for existing chemicals should be, as well as our concerns and comments regarding EPA's proposals under its Chemicals Assessment and Management Program (ChAMP).

Priorities:
- Focus on completing high-quality hazard characterizations of HPV chemicals.
- Fill gaps in hazard data for HPV Challenge chemicals.
- Target additional HPV chemicals lacking hazard data for data development.

Areas of concern:
- Lack of transparency and over-reliance on incomplete use and exposure information.
- Failure to act to control chemicals designated high-concern risk priorities by EPA.
- Proposal to rely on yet another voluntary initiative for inorganic HPV chemicals.

Additional areas of comment:
- Utility of screening and prioritizing medium-volume chemicals for hazard.
- Essential features of any effort to "reset" the TSCA Inventory.
- Value of publicly listing chemicals that may present an unreasonable risk.

What should EPA's priorities be for existing chemicals?

1. Focus on hazard characterizations: EPA should maintain a primary focus on developing and making publicly available high-quality and comprehensive stand-alone hazard characterizations (HCs) for HPV chemicals.
    - This is the unambiguous commitment made by EPA in adopting the 2005 NPPTAC recommendation. That document[1] clearly states that EPA will:

[1] See www.epa.gov/oppt/npptac/pubs/recommendationfeb2005.pdf.

- "conduct an objective evaluation of the quality and completeness of the data set in the HPV Challenge Program submission," including "a scientific review of all endpoint data" and "a determination as to the adequacy of the submitted data;"
- "independently assess the submitted data for each SIDS endpoint to determine the level of hazard;" and
- "develop [and make public] a hazard characterization of the substance(s).

- This task remains critical and should remain priority one. EPA's resources should be devoted, first and foremost, to completing this task. ***The HCs should not be decreased in scope or quality or pace of development and release, in the face of EPA's desire to proceed to also develop risk characterizations.***

2. Fill data gaps: ***By EPA's own accounting, 30% of the HCs EPA has posted to date[2] identify gaps in the data sets provided by sponsors, even though sponsors claim them to be final submissions.*** Our own analysis has identified data gaps for chemicals in at least several additional HCs. Yet EPA is virtually silent on what steps it intends to take to fill these data gaps, despite a pledge at the outset of the HPV Challenge that it would take all steps needed to ensure that full screening-level hazard data sets were developed and made public for all HPV chemicals.
   - EPA needs to proceed promptly and expeditiously to develop TSCA Section 4 test rules to require testing to fill all identified data gaps.
   - ***It is wholly inappropriate for EPA to proceed to develop risk characterizations and prioritizations that indicate a chemical is of low priority for further action in the face of gaps remaining in screening-level hazard data sets.*** Recall that the screening information data set (SIDS) used by the HPV Challenge is defined as the minimum amount of hazard data necessary to conduct a meaningful screening-level hazard characterization of a chemical.

3. Target additional HPV chemicals lacking hazard data: EPA's ChAMP documents claim that EPA will develop hazard and risk characterizations for about 2,750 organic HPV chemicals by 2012. ***Yet this estimate includes hundreds of HPV chemicals for which basic hazard data have not been developed under either the HPV Challenge or the OECD program.*** EPA is silent on how it intends to address the lack of hazard data for these HPV chemicals, which include:
   - About 270 "orphan" chemicals that were not sponsored, only 16 of which have been subjected to Section 4 test rules.[3] That rule took EPA more than five years to promulgate. EPA has yet even to propose a second test rule, which will apparently cover only about 40 orphans,[4] leaving more than 200 unaddressed.
   - Nearly 600 chemicals that reached HPV levels of production after the Challenge was launched but were not included in it.
     - These chemicals are supposed to be covered under the industry's unilateral Extended HPV Program (EHPV).

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[2] See http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=2. EDF examined each HC and tallied the number for which EPA identified one or more data gaps. Such gaps were identified in 30% (27 of 89) of the HCs posted to date.

[3] See www.epa.gov/chemrtk/pubs/general/regactions.htm.

[4] Presentation of Jim Willis, EPA Office of Pollution Prevention and Toxics, at the HPV Data Users Conference held in Austin, TX on December 12-14, 2006, www.newmoa.org/prevention/chemicalspolicy/hpv/materials.cfm.

- However, long after the December 2005 deadline for doing so, only about 230 EHPV chemicals have even been sponsored,[5] and hazard data have been made public for few if any of them.
- Industry has failed to live up to its commitments under the EHPV program to sponsor such chemicals, track commitments and rapidly develop hazard data and make them public.

- Hundreds more HPV chemicals that lack final or even initial submissions of data sets under the HPV Challenge or OECD program.[6]

At this rate, EPA will not even have hazard data for most of these HPV chemicals in the 2012 timeframe, let alone be in a position to have conducted the assessments it promises to deliver. These HPV chemicals need to be prioritized for the prompt development of hazard data, including through development of Section 4 test rules where necessary. This task warrants a much higher priority than EPA's apparent rush to develop risk characterizations.

Major concerns with and additional comments on EPA's ChAMP Initiatives

Our comments and major concerns with EPA's other current and proposed activities under ChAMP are discussed below.

4. Reliance on use and exposure data from the IUR: Starting in 2006, EPA began collecting limited use and exposure information under its Inventory Update Rule (IUR).[7] The IUR data themselves have yet to be made public, yet EPA is already heavily relying on this information to develop its risk characterizations of HPV chemicals. Several major problems are already apparent:

A. Lack of transparency: We are extremely concerned that the actual extent of use and exposure information available to EPA is being denied and not transparently communicated to the public, for at least two reasons: First, EPA's over-deference to the extensive claims of confidential business information (CBI) made for such information; and second, EPA's failure to clearly indicate what specific reportable information elements were not submitted because they were not "readily obtainable" by the manufacturer (which, in our view, constitutes a major loophole in the IUR reporting regulations). ***In five of the eight risk decision documents posted to date, EPA indicates that at least some of the requested use and exposure information was not reported because manufacturers said it was not "readily obtainable."*** In most cases, EPA has not specified what information elements are missing. Yet it has proceeded to draw risk conclusions anyway, and has not indicated any action it will take to obtain the missing data.

B. EPA allows IUR data to trump all other use information: ***Even in cases where IUR data are contradicted by other use data, EPA has relied only on the IUR data.*** For example:

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[5] See www.americanchemistry.com/S_ACC/sec_policyissues.asp?CID=432&DID=1493.

[6] See Denison, R.A., *High Hopes, Low Marks: A final report card on the High Production Volume Chemical Challenge*, Environmental Defense Fund, July 2007, at www.edf.org/hpvreportcard.

[7] See www.epa.gov/oppt/iur.

- In the case of n-Butyric acid, EPA reported data that indicated the chemical is used as a food additive and an ingredient in varnish, cosmetics and detergents, as well as a chemical intermediate. Yet EPA ranks both exposure and risk to commercial workers, consumers and children as low because "*the IUR data* indicate that exposure to butyric acid in these products is not expected because all (100%) of the production volume for both chemicals is reported to be used as an intermediate" (emphasis added). That is, EPA relies exclusively on data for a single year's production self-reported only by those by manufacturers that fall above the reporting threshold (of 25,000 pounds per year) to discard other data it possesses indicating that uses exist that would clearly pose risks of human exposure, including to children.
- In the case of Dimethyl succinate (DMS), EPA cites publicly available (not IUR) data from a 2007 source indicating that a "major use" of the chemical is as a food additive. Using other non-IUR public data from 2004 and 2007 sources, EPA also reports that DMS (as well as two other members of the same chemical category) is used in products ranging from paint strippers to polishes to lacquer thinners. Because of such use in products, EPA ranks consumer exposure potential to DMS high. But it then ranks children's exposure potential as low, stating: "*Based on IUR data*, the likelihood that DMS, DMA and DMG will be used in products intended for use by children is low" (emphasis added). No description is given of what type of information received under the IUR would support such a conclusion. ***Moreover, this single sentence – plus one other sentence asserting "The paint stripping consumer use described above is not likely to involve children" – constitutes the entirety of EPA's exposure assessment for children.*** Even this latter, highly questionable assertion does not address the "major use" of DMS as a food additive, which obviously will lead to children's exposure.

Addressing transparency: EPA should publicly release, for each chemical, a list of the required IUR reporting elements that specifies, for each element, whether:

i) information was submitted and claimed CBI,
ii) information was submitted and not claimed CBI (and hence should be made public), or
iii) information was not submitted because it was deemed by the submitter not to be "readily obtainable."

This information should be included ***both*** in EPA's public release of the IUR data, and in any exposure or risk characterizations it develops for specific chemicals that use IUR data.

Appropriate use of IUR data: Where EPA has received incomplete use and exposure information for a chemical, whether because it was deemed "not readily obtainable" or otherwise, EPA should:

i) not rely on it to develop risk characterizations or draw risk conclusions;
ii) publicly acknowledge the lack of sufficient information, including providing overall statistics on the extent of information it did and did not receive under the 2006 IUR; and
iii) promptly initiate steps to gain or supplement such information, e.g., through issuance of TSCA Section 8 reporting rules.

Finally, EPA has an obligation to be forthright and forthcoming with respect to the limitations of the IUR, rather than seek to obscure the actual extent and utility of the use and exposure information the IUR has yielded. Only in this way can it be improved.

5. Other deficiencies in risk characterizations and prioritizations: To date, EPA has posted eight risk-based prioritization documents and associated support documents, covering 19 HPV chemicals (some are in categories).[8] Beyond the lack of transparency and the reliance on incomplete use and exposure information just noted, we find very disturbing other aspects of EPA's risk decisions. In addition to the two earlier examples provided, consider the following outcomes of EPA's risk decisions:
    - In at least two cases, EPA has assigned low risk priorities to chemicals that possess significant hazards to human health, based on only limited evidence of low exposure.[9] In one of these cases, the Dicarboxylic acids category, members of the category found to cause moderate to severe eye irritation were deemed to pose only a low risk concern to workers. This conclusion was based solely on an unsupported presumption that "standard industrial hygiene" procedures would both be used and be adequate – ***this despite the fact that worker exposure-related information was not submitted by the manufacturer because it was deemed not "readily obtainable."***
    - In three of the eight cases, EPA assigned a high-priority risk concern based on evidence of both significant hazard and exposure potential.[10] ***Astoundingly, even in these cases, EPA's follow-up action is to "encourage companies to provide available information on a voluntary and non-confidential basis"!*** Is this really what EPA meant when it made the commitment under the Security and Prosperity Partnership (SPP) to "assess and initiate needed action" on existing chemicals?[11]

6. Another Challenge program for inorganic HPV chemicals: For those inorganics that are HPV chemicals, EPA proposes yet another voluntary Challenge. The HPV Challenge, which was supposed to have been completed in 2005, is far from done and has fallen well short of the promises made by EPA and industry (see our recent report, ***High Hopes, Low Marks***, www.edf.org/hpvreportcard). The Extended HPV Program is by all visible measures a dismal failure. ***There is simply no basis for confidence in EPA's or industry's performance in yet another voluntary program, and EDF opposes initiation of such a program.*** EPA should instead seek to require the needed testing of such chemicals, using its TSCA Section 4 authorities. We recognize that EPA may not be able to make the requisite findings for many of these chemicals. EPA should therefore also acknowledge the need for – and support – an expansion of its statutory authority to require data development.

7. Screening MPV Chemicals: EDF generally supports the approach EPA intends to take for medium production volume (MPV) chemicals: Utilize available data – including those developed through the Canadian DSL Categorization process – along with the tools and

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[8] See http://iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=1.

[9] These cases are Dichloroacetyl chloride (DCAC) and the Dicarboxylic acids category. For the former of these cases, EDF provided extensive comments to EPA on an initial draft of its risk characterization and prioritization documents, to little avail. Our comments on drafts of EPA's risk documents are available upon request.

[10] These cases are Ethane,1-1'-oxybis[2-methoxy- (also known as diglyme); Hexabromocyclododecane (HBCD); and Ethane, 1,2-dimethoxy- (also known as monoglyme).

[11] See www.epa.gov/champ/pubs/basic.htm#07commit.

approaches EPA applies to new chemicals, to screen MPV chemicals for hazards and prioritize them for further action. (This approach is quite similar to one that I and several other members of NPPTAC proposed to EPA in 2005.[12] Unfortunately, strident opposition at that time from NPPTAC's industry members and from EPA itself led to the demotion of this concept from a recommendation to an option for EPA to consider. It is with more than a little irony, therefore, that I note such strong support emanating from EPA and industry for this re-born element of ChAMP.)

While we support this approach in the face of the enormous constraints under TSCA on EPA's ability to require the development of robust data on such chemicals, let me be clear: ***We consider it far from ideal for EPA to have to resort to trying to prioritize chemicals on the basis of existing information that is clearly incomplete and often of low quality. It would be far preferable first to develop consistent and robust information on chemicals in commerce, and then to use that information to set priorities.*** The latter approach, taken by the European Union's REACH Regulation, is far different from what EPA is planning to do, and EPA's efforts to argue the approaches are comparable in scope and timing is disingenuous at best. We fully recognize that EPA is unable to take such an approach under TSCA – which is among the many reasons we are calling for major reform of U.S. chemicals policies.

It is worth noting that Canada's DSL Categorization, the results of which EPA now proposes to heavily rely on to screen MPV chemicals, was also limited to consideration of already existing information. As a result, that process identified thousands of chemicals for which no or only low-confidence categorization decisions could be made.[13] Canada has only about 2% of the global chemicals market, compared to the U.S.'s 20-25% share; it also heavily relies on imports rather than domestic production. It can be argued that these factors render quite reasonable the decision by Canada to undertake a more limited effort than that under REACH. In contrast, the U.S., with a larger share of commerce in chemicals, greater domestic production and a much larger population and economy, can and should do more.

8. Resetting the Inventory: EPA proposes to determine, through unspecified means, which chemicals listed on the TSCA Inventory are still in commerce, and which are no longer. In principle, getting a better handle on which Inventory chemicals are in commerce could have value. However:
    - ***Any Inventory resetting must be done using a reporting mechanism that tracks production/import over a significant period (at least 5 and ideally 10 years).*** EPA's experience with IUR reporting of production and import data – which entails the reporting of only one year's volume once every five years (recently raised from every four years) – shows that there is enormous fluctuation from one reporting cycle to the next that must reflect underlying changes in chemical supply and demand dynamics and production and use patterns.[14] These data demonstrate that infrequent and time-

[12] See Option D on pp. 13-15 of the "Initial Thought-Starter" document posted on the NPPTAC website at http://www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf. NPPTAC, the National Pollution Prevention and Toxics Advisory Committee, advised EPA's Office of Pollution Prevention and Toxics.

[13] See, for example, Environment Canada's decision summary at www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm.

[14] USEPA, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, "Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" Draft dated October 6, 2005, pp. 3-4, at www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf; and Environmental Defense comments on

limited reporting yields a highly inaccurate picture of which chemicals are in commerce, as well as their actual manufacturing levels over time. Reliance on one-time reporting over a limited window to reset the inventory simply won't do the job, and will significantly underestimate the number of chemicals in commerce.

- ***No lower threshold should apply to the reporting used to reset the Inventory.*** Production or import of a chemical in any amount at any time during the reporting window should trigger retention on the Inventory if its original purpose is to be retained. EPA already has a system that employs a threshold for regular, if infrequent, reporting: the IUR.[15]

- ***Any chemicals removed from the Inventory must not be "lost."*** Many such chemicals, even if not in active production, may nevertheless still be stockpiled, present in products as ingredients, byproducts or residuals, or present as pollutants in air, water, soil, sediment or waste sites. And of course, they may return to active production in the future. It is critical that EPA retain, and the public still have access to, any and all information available on such chemicals.

- ***Any chemicals removed from the Inventory must be subject to TSCA Section 5 notification requirements.*** There are several reasons to take this approach. First, without it EPA will inadvertently create a substantial incentive for companies to seek ways to be removed from the Inventory, so as not to be subject to reporting or other requirements applicable to Inventory chemicals. Creating such a dynamic – or even the perception of it – will only serve to call into question the reliability of the resulting listing.

  Second, subjecting companies who commence (or recommence) manufacture or import of a removed chemical to Section 5 requirements would help to address a major deficiency under TSCA – namely, the significant barriers EPA must face in order to address any of the tens of thousands of existing chemicals in commerce. A review of potential risks prior to re-entry of such chemicals into commerce could be conducted. For such chemicals anticipated to re-enter commerce, standard industry arguments that a high bar should apply before initiating actions that could harm the economic position of a chemical already in commerce clearly would obviously not apply.

  Third, the number of such chemicals presumably would be small, presenting little additional burden on EPA to review them. (If the number of such chemicals proved to be large, that would argue that EPA's rationale for resetting the Inventory in the first place was faulty, or that there was significant under-reporting in the resetting process.)

  Two options are possible to ensure Section 5 would apply to removed chemicals. In developing its rule to reset the Inventory, EPA could set forth this requirement as unambiguous policy: As has been the case historically, any chemical not on the Inventory is subject to Section 5 requirements. Alternatively, EPA could issue one or

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Proposed Rule, TSCA Inventory Update Reporting Revisions (70 Fed. Reg. 3658, 26 January 2005), Docket ID No. EPA-HQ-OPPT-2004-0106, accessible at www.regulations.gov (search for docket number).

[15] EPA recently raised the IUR reporting threshold from 10,000 to 25,000 pounds annually.

more Significant New Use Rules (SNURs) to cover such chemicals; this latter approach is similar to that taken by Canadian authorities for priority chemicals found no longer to be in commerce in Canada.

9. Use of never-before-used TSCA Section 5(b)(4) listing authority: This is a useful concept that is worthy of serious consideration. However, other than pointing to the "presents or may present an unreasonable risk" language in TSCA, EPA has yet to discuss what criteria it would use to decide what chemicals to list. Without the development of such criteria up front, the process will be highly subjective and lack transparency and accountability.
    - EPA should pursue this concept through a transparent, public process.
    - That process should lead to the development and publication of clear criteria specifying hazard, use and/or exposure characteristics that will be used to identify chemicals to be listed.

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