

Draft Proposed Universe to PCCL Process

Introductory comments:

First, the definition of a "gate" is a path from the universe to being included on the PCCL. We are only addressing universe to PCCL here. Our discussions so far of PCCL to CCL seem to be more focused (directed toward a combination of automaton and expert input) so we are not addressing that step here.

The purpose of this "reorganization" is:

1. To make the nomenclature consistent with the NAS/NRC documents
2. To build a "framework" for our discussions (With each gate defined we can approach how to make the gate work (e.g.--a calculation, comparison, discussion, etc.)
3. To make our "gates" line up with the data coming at them from the Data Working Group (They seem to be building from the NAS/NRC approaches, so we should start off with data streams and gates that will be at least partially aligned). We can define the paths, suggest additional ones, and start to evaluate how well they work.

Universe to PCCL

The "total universe" is of unknown size, but the "defined universe" we will be working with is what we know or can imagine (hence it is growing all the time). The Data Working Group is defining this "known universe" mostly using a "bottom up" approach--i.e.--by using available information to define its members (and a periodic review process to include new members). It is this known universe from which we start. However, it is important to note that not every member will be fully characterized as a contaminant or of known distribution or effect. Some contaminants will be identified and possibly included by surrogate data, such as production data, or by other educated guesses.

The purpose of the gates is then to narrow down the known universe to a more manageable number, the PCCL. The NAS/NRC approach provides a good basis for doing this, although we may make some modifications and additions. (see pages 85-88)

The following four gates are based on the Venn diagram of the NAS, page 82. Each gate reflects one of the intersections of this Venn diagram. The words used to describe these gates, either demonstrated or potential are from the NAS. The definitions of the terms potency and magnitude can be found on NAS pages 95 and 99, respectively.

A chemical that does not pass any of these gates would remain in the universe; ones that pass the test get onto the PCCL.

The two criteria are occurrence and effect. A contaminant must have demonstrated or potentially significant occurrence at a level to have demonstrated or potentially significant effects (both things) to get onto the PCCL. The rationale is discussed in the NAS book around the pages of the above diagram.

We have discussed the need for some extra gates, or at least one that is a "nomination" process where a contaminant can be added because experts think it should be. We can define more gates as needed, for example, Gate 5 for a nomination process. That, and more, can be done.

The challenge is to come up with ways to "mechanically" screen the large number of contaminants in the universe to make it a manageable task, essentially using a rule-based approach in all or most cases. Our problem is to have a way to characterize the criteria of occurrence and effect so that we end up with a list that satisfy both criteria, which then get onto the PCCL. Characterization is easiest if we quantify as much as possible the criteria of occurrence and effect (based on SARs, production data, etc., and, of course, actual occurrence data when available). The use of the term "demonstrated" below infers actual direct data and a higher level of confidence in the assignment. The term "potential" means estimated, based on indirect methods, or suspected, and infers less confidence in the assignment.

The NAS/NRC book discusses some approaches to dealing with the contaminants for which we do not have demonstrated occurrence and effect data (most of the potential contaminants!) on pages 85-88. These are examples of the input to the "rules" we need to be developing and testing.

Below are some examples, but there will be more as we look at the data types coming from the Data Working Group. The next step is defining the ways we want to use actual data to make these gates work. Again, the information in the NAS book is very useful.

In Case Where Have No Data and/or Information

We discussed what to do if we have "no" data and have no "information" on a contaminant? In this case, do nothing. What we mean by no data is that we have no health effects studies or no water samples in which this contaminant is detected.

Data on the occurrence side means we have actual measurements in water; data on the health effects side means toxicity tests/results or other similar studies. Information means we have some way of estimating these things or reasonably predicting their existence.

If we have no data and cannot make an assessment or estimate sufficient to constitute "information" the compound does not get onto the PCCL. If we have some information that is sufficiently compelling (e.g. chemical structure similar to Dioxin but no data or information) it can be nominated through Gate V.

A question is, if we have structure or know some information, is this adequate for some routine consideration, like Gate IV? A following question is, at what point should you consider a very small amount of data adequate to make a determination if it should move to PCCL through, ie, Gate II, III, or IV below.

Have Some Data or Information

Gate I. Have health effects data and concentration data.

We know it is there and that it can cause problems. Is it there at high enough concentrations to be of concern?

e.g.- Is the demonstrated (actual data) maximum concentration in water of the contaminant greater than the demonstrated (known) safe dose? If yes, then it is on the PCCL with high confidence.

- We need to define “what is safe”.

Alternatively, is the maximum concentration less than the threshold of concern? -then it is not on the PCCL. (Note: Triggers can be based on a number of criteria, so we need to discuss this. For example, something can be off the list if the maximum plausible concentration is less than a threshold of concern, or on the list if a plausible or likely concentration is above the threshold of concern. In some cases it might be shown that a plausible maximum concentration is above the threshold, and therefore the contaminant should make it to the PCCL. Other possibilities exist, including statistical and probability treatments, but the data required are probably not available.

Gate II. Have concentration data and health effects information.

We know it is there, and suspect it may cause problems. Is it there at high enough concentrations to be of concern?

e.g. Is the demonstrated maximum concentration in water of the contaminant greater than a potential safe dose based on some estimate? If yes, continue onto the PCCL with medium confidence.

Alternatively...see alternative in Gate I above.

Gate III. Have health effects data and concentration information.

We suspect it may be there, and know it can cause problems.

Is the potential plausible maximum concentration in water of the contaminant greater than a demonstrated known or other safe dose? If yes, continue onto the PCCL with medium confidence.

Alternatively...see above...

Gate IV. Have information on adverse health effects and possible occurrence, but have no data. Have some indicator of a need to worry. (e.g., contaminant likely to reach watersheds or sources and is soluble but we can't analyze for it and it has suspected health effects but no data) It may be there, and it may cause problems.

Is the potential maximum concentration in water of the contaminant greater than the potential safe dose?

If yes, continue onto PCCL, but with low confidence.

Alternatively.....see above

Gate V. Find out something in future, have alternative nomination process.