Overall, 93 waivers were granted that reduced animal use by at least 3,325 animals used in Tier 1 tests performed on the List 1 chemicals.

This study characterizes the types of OSRI submissions that EPA considered during the Tier 1 testing of 67 List 1 chemicals.

A guidance document released in September 2011, which contained the principles and procedures for Tier 1 testing, specified that EPA may consider certain types of other scientific relevant information (OSRI) in lieu of the Tier 1 test battery.

OSRI could be directly equivalent to that generated by the Tier 1 assay, or it could be functionally equivalent, i.e., data of a suitable nature and quality to provide essentially the same predictive information about a chemical.

With the large number of chemicals slated to be tested in the EDSP, it is essential that EPA develop consistent guidance on the use of OSRI.

With the exception of the ER binding and uterotrophic assays, most waivers were based on studies conducted using the same or similar protocol.

Most waivers showing a negative response were based on studies conducted using the same or similar protocol as the Tier 1 assay.

Similarly, six of the seven uterotrophic assay waivers showing negative responses were based on assays conducted using the same or similar protocol to the Tier 1 test.

The seemingly inconsistent responses by EPA may be due to a strict interpretation of “other relevant information” to mean the same information that would be obtained from a Tier 1 assay, perceived or assumed lack of sensitivity, and potential inconsistencies among EPA staff in how OSRI was evaluated, underscoring the need for clearly articulated, transparent criteria for accepting OSRI.

Due to the low rate of acceptance of OSRI by EPA, the waivers granted saved only a relatively small number of animals from Tier 1 tests.

With the large number of chemicals slated to be tested in the EDSP, it is critical that EPA develop consistent guidance on the use of OSRI.

With the agency's plans to eventually use 21st Century Toxicology tools to screen for endocrine disruptors, OSRI will still be an important means for saving animals and avoiding duplicative testing as it can support the results of Tox21 methods and lend confidence to the accuracy of their predictions.