

QUESTIONS & ANSWERS

Q1. What has changed in the revised Request for Proposal attached as amendment one ?

- A1.** The Revised Request for Proposal (RFP) attached as amendment one should be regarded as the official RFP and replaces in whole the version posted on June 6. The main changes are:
- 10 additional points are available to be earned when demonstrating experience asked for under Point-rated Criteria R1 if that experience involves "in vitro dermal absorption testing over a 72-hour period"
 - bidders are to provide six (6) quotes (up from three), that convey the cost of conducting the study depending upon whether Health Canada decides to use **one, two or four** doses for the testing and whether the chemicals are to be tested for **24 or 72 hours**
 - the method of comparing cost proposals has been changed so that Health Canada will only compare the costs of doing the study with two doses for 24 and 72 hours. The two quotes will be added together and the bidder with the lowest sum will score the maximum points allocated to the cost section of the evaluation, while the other bidders will receive a pro-rated score
 - the "closing date" for receiving bids has been pushed back to July 15, 2016

Q2. There are several ways of conducting dermal absorption studies – infinite dose under occluded conditions, finite dose under unoccluded conditions, 24 h vs 72 hr mass balance, etc. Which of these conditions will be applied to chemicals listed in the bidding document and how?

- A2.** We are expecting the vendors to propose a study design based on their expertise taking into account the test chemical listed in the bidding document and the vehicle in which it may be applied to the skin. It is ideal if a study design can mimic real-life exposure as closely as possible taking into account the information related to the uses of products containing the chemicals listed in the bid and the concentrations at which they are used. However, it is important that the design (infinite vs finite, occluded vs unoccluded, vehicle used, 24 h vs 72 hr, timing of mass balance, etc.) should be justified.

Q3. Is it required to conduct dermal absorption testing over 72 hours for all chemicals listed in the bidding document?

- A3.** It is not essential that all chemicals listed in the bidding document be tested over 72 hr period of time. Terminal post-exposure time point may vary depending on specific substance and the formulation. While a sampling period of 24 hr is adequate to characterise the absorption profile of most chemicals, some chemicals may require an extended sampling period. Thus, it is required that the bidder has the necessary experience conducting the testing over an extended period of time.

Q4. Are the applications dilutions of the neat chemical?

- A4.** In terms of a generic procedure, it is correct that we are referring to dilutions of the neat chemical.