

## Elements of an Offer to Pay for the Use of Inert Ingredient Data

While EPA does not have regulations or forms setting forth the precise language to be used in offers to pay that address compensation obligations for data protected by FFDCA section 408(i), EPA believes it is appropriate to look to the FIFRA data compensation regulations as a guidepost for section 408(i). Accordingly, EPA believes the approach set forth at 40 CFR 152.93(b)(2) will generally be sufficient for offers to pay for data protected by FFDCA section 408(i). Thus, if the offer to pay addresses/includes the following, EPA would likely deem it sufficient for purposes of section 408(i):

1. The offer should clearly identify the ingredient in question (including the Chemical Abstracts Service Registry Number if one exists) and that the offeror intends to market the ingredient as a pesticide inert ingredient.
2. The offer should clearly identify the studies for which the offer to pay is being made. For example, the offeror could choose to broadly identify the studies by reference to all studies submitted to EPA in support of a specific action (e.g., "all studies submitted by [original data submitter] to EPA in satisfaction of the data call-in of [date]"). Alternatively the offer could list the specific studies by means of Agency Master Record Identification Numbers. (See also 40 CFR 152.86 and 40 CFR 152.90 for further guidance on these methods of data citation.)
3. A clear statement that the offeror agrees to pay the original data submitter for use of the data to the extent required by FFDCA sec. 408(i) and to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of the data.
4. The offeror's name, address, telephone number and email address.
5. A copy of the offeror's letter should also be submitted to EPA together with proof of receipt by the original data submitter. While this is not a requirement under FIFRA, EPA does not yet have certification forms that serve as a substitute for such proof and therefore believes it is appropriate to ask for copies of both the offer to pay and proof of receipt of the offer to pay. EPA may in the future develop forms that can be used to demonstrate compliance with section 408(i).