

ANNEX 3

REQUIRED ELEMENTS OF A COMPREHENSIVE PROPOSAL

- (1) A comprehensive proposal shall include adequate documentation containing the following:
 - (a) developments in the data cited in the initial proposal;
 - (b) findings from the categories of data set out in paragraphs (3)(a), (b) and (c), as applicable, depending on the subject of the proposal and the identification or description of the methodologies under which the data were developed;
 - (c) a summary of the results of studies conducted on the adverse effects of the anti-fouling system;
 - (d) if any monitoring has been conducted, a summary of the results of that monitoring, including information on ship traffic and a general description of the area monitored;
 - (e) a summary of the available data on environmental or ecological exposure and any estimates of environmental concentrations developed through the application of mathematical models, using all available environmental fate parameters, preferably those which were determined experimentally, along with an identification or description of the modelling methodology;
 - (f) an evaluation of the association between the anti-fouling system in question, the related adverse effects and the environmental concentrations, either observed or expected;
 - (g) a qualitative statement of the level of uncertainty in the evaluation referred to in subparagraph (f);
 - (h) a recommendation of specific control measures to reduce the risks associated with the anti-fouling system; and