expanded discussion of information of impurities:

(1) From other possible chemical reactions;

(2) Involving other ingredients; or

(3) At additional points in the production or formulation process.

§ 158.170 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

§ 158.175 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

If the nominal concentration (N) for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper limit	Lower limit
$N \leq 1.0\%$	$N + 10\%N$	$N - 10\%N$
$1.0\% < N \leq 20.0\%$	$N + 5\%N$	$N - 5\%N$
$20.0\% < N \leq 100.0\%$.	$N + 3\%N$	$N - 3\%N$

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicant must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale of distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the