Ohio EPA Policy DSW-0700.007 **Removed**	**Additivity Factor Equation for Carcinogens**	
	Statutory references: Rule references:	Ohio EPA, Division of Surface Water Revision 0, July 30, 1990 Revision 1, September 30, 1999 Removed, December 21, 2006
THIS POLICY DOES NOT HAVE THE FORCE OF LAW Pursuant to Section 3745.30 of the Revised Code, this policy was reviewed and removed.		

This policy does not meet the definition of policy contained in Section 3745.30 of the Ohio Revised Code. Ohio EPA is removing this document from the Division of Surface Water Policy Manual and is considering addressing this topic in internal guidance.

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Ohio EPA Policy DSW-0700.007 **Final**	**Additivity Factor Equation for Carcinogens**	
	Statutory reference: ORC 6111.03 Rule references: OAC 3745-2-06, OAC 3745-2-07, OAC 3745-33-07	Ohio EPA, Division of Surface Water Revision 0, July 30, 1990 Revision 1, Spetember 30, 1999

THIS POLICY DOES NOT HAVE THE FORCE OF LAW
Pursuant to Section 3745.30 of the Revised Code, this policy was reviewed on the last revision date.

Purpose
To describe screening procedures used when evaluating the need to include an additivity factor equation in an NPDES permit.

Background
Where more than one carcinogen is in a discharge, the additive risk of the carcinogens in the discharge must be evaluated. OAC rule 3745-2-07 contains the procedures whereby an additivity factor (A.F.) equation is determined. This policy describes the procedures to screen the A.F. equation to determine whether the permit support document should recommend inclusion of the equation in a permit.

Procedure
The A.F. equation consists of two or more quotients. These quotients, when summed, must not exceed 1.0. This ensures that the incremental increase in risk due to the exposure to these carcinogens does not exceed 10^{-5}. Although an A.F. equation can be determined whenever there are two or more carcinogens considered in a wasteload allocation (WLA), there are situations in which the inclusion of an A.F. equation in a permit does not result in any increased environmental protection. A screening must, therefore, be performed to determine whether an A.F. equation is necessary. This screening involves three procedures.

<u>Procedure 1</u>

An A.F. equation is not needed in a permit where the degree of protection provided by the equation is less than that provided by the other limits in the permit. This is analogous to the situation where there are both aquatic life and human health water quality criteria. As part of the WLA, only the more restrictive of the aquatic life and human health limits is recommended for inclusion in a permit.

Thus, before an A.F. equation is recommended to be included in a permit, a screening should be done to determine that the A.F. results in more restrictive requirements than the other limits in the permit. For example:

Example 1

Carcinogen	WLA Results: Aquatic Life	WLA Results: Human Health	Effluent Limit
A	15	100	15
B	40	200	40

If the effluent were to contain the maximum concentrations allowable, i.e., 15 for carcinogen A and 40 for carcinogen B, the incremental cancer risk would be:

$$\frac{15}{100} + \frac{40}{200} = 0.35.$$

Since the incremental cancer risk will be less than 1.0 if the discharger is in compliance with the rest of the permit, the A.F. equation is not a limiting factor and is not needed in the permit.

If only average or both average and maximum effluent limits are given, average limits are used in this screening; if only maximum effluent limits are given, the maximum limits are used in the screening. Concentrations should be used in the screening whenever possible. Loadings may be used when concentrations are not available.

Procedure 2

Where an effluent limit for a carcinogen is less than the detection level, that carcinogen should not be considered in the A.F. equation. For purposes of this procedure, the detection levels used should be those reported by the Ohio EPA Division of Environmental Services. For example:

Example 2

Carcinogen	WLA Results: Aquatic Life	WLA Results: Human Health	Effluent Limit	Detection Level
A	15	100	15	5
B	40	200	40	5
C	5	1	1	5

The screening equation then becomes:

$$\frac{15}{100} + \frac{40}{200} + \frac{1}{1} = 1.35.$$

In the regulatory process when addressing limits less than the detection level, assumptions are made. First, any detectable amount of the substance is considered a permit violation. Secondly, measurements reported as less than detection are treated as in compliance. Measurements below detection are not considered in the A.F. equation (i.e., measurements below detection are treated as zeros). Therefore, when the effluent concentration for carcinogen C in Example 2 is less than detection (i.e., less than 5), the quotient for carcinogen C is zero and does not contribute to the A.F. equation. When the effluent concentration for carcinogen C is detectable (i.e., greater than or equal to 5), there is a violation of the effluent limit of 1 for that carcinogen. There will also be a violation of the A.F. but there is no need to have two violations.

This is analogous to the example where an effluent concentration violated both the aquatic life and human health water quality criteria. If the Agency were to include limits for both the aquatic life and human health criteria for a chemical in a permit, there is a possibility that an effluent concentration could violate both limits. Rather, the Agency applies only the more restrictive limit in the permit. In Example 2, the effluent limit for carcinogen C is equally restrictive as the A.F. equation that includes a quotient for carcinogen C. Therefore, one but not both of these should be in the permit.

After quotients for carcinogens with limits less than the detection levels are eliminated from the A.F. equation, the remaining equation is evaluated as in Procedure 1. The A.F. equation has been reduced to:

$$\frac{15}{100} + \frac{40}{200} = 0.35.$$

Since the A.F. is less than 1.0, the A.F. equation is not needed. In this example, the only way that the discharge can pose an incremental cancer risk of greater than 10^{-5} (i.e., have an A.F. greater than 1.0) is if there is a violation of one or more of the chemical specific effluent limits.

The following example illustrates the application of Procedures 1 and 2 with an outcome to recommend inclusion of the A.F. equation in the permit.

Example 3

	WLA Results			
Carcinogen	Aquatic Life	Human Health	Effluent Limit	Detection Level
A	15	100	15	5
B	40	200	40	5
C	5	1	1	5
D	20	4	4	5
E	60	10	10	5

After eliminating the quotients for carcinogens C and D because the effluent limits for these carcinogens are below the detection levels, the screening equation becomes:

$$\frac{15}{100} + \frac{40}{200} + \frac{10}{10} = 1.35.$$

Since compliance with the effluent limits cannot ensure that an A.F. of 1.0 is not exceeded, the A.F. equation is needed in the permit.

Procedure 3

If there are several carcinogens in the effluent, the A.F. could potentially be cumbersome. One or more of the quotients in the A.F. equation may contribute only a very small portion to the A.F. The A.F. equation can be simplified where "insignificant" or "de minimis" quotients are present. The decision has been made that any one quotient or combination of quotients that totals 0.1 or less is de minimis and can be eliminated from the A.F. equation. The total eliminated by this procedure must not exceed 0.1.

Example 4

	WLA Results		
Carcinogen	Aquatic Life	Human Health	Effluent Limit
A	15	100	15
B	40	200	40
C	90	50	50
D	10	200	10
E	5	400	5

The screening equation is:

$$\frac{15}{100} + \frac{40}{200} + \frac{50}{50} + \frac{10}{200} + \frac{5}{400} = 0.15 + 0.20 + 1.0 + 0.05 + 0.0125 = 1.4125.$$

Provided that the individual effluent limits for carcinogens D and E are included in the permit, the quotients for D and E can be eliminated from the A.F. equation (since the sum of the quotients for D and E is less than 0.1). The screening equation then becomes:

$$\frac{15}{100} + \frac{40}{200} + \frac{50}{50} = 1.35.$$

Therefore, the A.F. equation, containing quotients for carcinogens A, B and C, is necessary in the permit.

These three procedures used together may eliminate the need for an additivity equation as shown in the following examples.

Example 5

	WLA Results			
Carcinogen	Aquatic Life	Human Health	Effluent Limit	Detection Level
A	15	100	15	5
B	40	200	40	5
C	5	1	1	5
D	20	4	4	5
E	3	90	3	5

After eliminating the chemicals with effluent limits below the detection levels from the equation, the screening equation becomes:

$$\frac{15}{100} + \frac{40}{200} = 0.15 + 0.2 = 0.35.$$

No A.F. equation is needed in the permit.

Example 6

Carcinogen	WLA Results: Aquatic Life	WLA Results: Human Health	Effluent Limit	Detection Level
A	10	100	10	5
B	40	20	20	5
C	5	1	1	5
D	20	4	4	5
E	3	90	3	5

After eliminating the chemicals with effluent limits below the detection levels from the equation, the screening equation becomes:

$$\frac{10}{100} + \frac{20}{20} = 0.1 + 1.0 = 1.1.$$

The quotient for carcinogen A is considered de minimis and is eliminated from the equation. This leaves only the quotient for carcinogen B. Since an A.F. equation is not needed when it includes only one carcinogen, the A.F. equation is not needed for this permit.

When applying these procedures, a few precautions must be taken.

1) Before the A.F. equation is eliminated in a permit, the following question should be asked: Do the chemical specific limits in the permit ensure that an exceedance of the A.F. of 1.1 will result in a violation of one or more of the chemical specific limits. If the answer is yes, then the A.F. equation is not needed. If the answer is no, the A.F. equation is needed.

2) Although in all the above examples, only aquatic life and human health WLA results are included, it is the final recommended effluent limits that are used in the A.F. screening equation. These effluent limits may be based on agricultural water supply criteria or an antidegradation analysis rather than aquatic life or human health criteria. If any limits in the final permit are less stringent than the limits used in the screening, such as when antidegradation based limits are made less stringent for important social or economic development, the screening equation should be reevaluated. Also, if any limits in the final permit are more stringent than the limits used in the screening, such as through the imposition of technology limits, the A.F. equation may not be needed.

3) Since the sum of the quotients for several carcinogens may be significant, all carcinogens suspected to be present in an effluent should be evaluated in this screening process. After these screening procedures have been done, a determination must be made with regard to each carcinogen whether to recommend that the permit contain a limit, monitoring requirements or neither. These decisions will be made consistent with OAC

Chapters 3745-2-06 and 3745-33-07. Each carcinogen in an A.F. equation that appears in a permit must also have a chemical-specific limit or monitoring requirement.

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