

CLIENT ALERT

EPA to Expand Chemicals Testing for Endocrine Disruption

November 16, 2010

On Wednesday, November 17th, the Environmental Protection Agency (EPA) will publish in the Federal Register a list of 134 additional chemicals being considered for "Tier 1 screening" tests under the Endocrine Disruptor Screening Program (EDSP). The list of chemicals being proposed for testing includes a large number of pesticides, two perfluorocarbon compounds (PFCs), and three pharmaceuticals (erythromycin, nitroglycerin, and quinoline). The list also includes an array of other chemicals, ranging from those used for industrial manufacturing processes, as plasticizers, or in the production of pharmaceutical and personal care products (PPCPs). The complete list of 134 chemicals can be found at the bottom of this alert.

You may be potentially affected by this notice if you produce, manufacture, use, consume, work with, or import any of the 134 chemicals on the list. EPA is allowing for a 30 day comment period to receive information that may inform the exclusion or inclusion of the chemicals on the second EDSP list.

EPA developed EDSP in response to a Congressional mandate in the Federal Food, Drug, and Cosmetic Act (FFDCA) "to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as [EPA] may designate" (21 U.S.C. 346a(p)). As part of EDSP, EPA issues orders to collect certain test data on listed chemical substances. Test data requirements are derived from specific test assays, which are divided into two tiers. Tier I test assays (the subject of the November 17th notice) are used to "screen" the chemicals for interaction with the estrogen (E), androgen (A) or thyroid (T) hormonal systems. Tier II test assays may be required for some of the chemicals listed and are intended to test for more specific chemical effects on the endocrine system, and are currently in the process of being developed and validated.

EPA issued the first list of chemicals of 67 chemicals under the EDSP on April 15, 2009. This list included 58 pesticides and 9 high production volume chemicals and/or inert ingredients of pesticide products. The test screens are estimated to cost approximately \$1,000,000/chemical. Industry has raised numerous concerns about the EDSP including:

- Test guidelines that are overly prescriptive and inflexible;
- Overly stringent test validation criteria that could lead to repeating otherwise technically sound studies;
- Screening tests with highly variable test endpoints that could easily result in false positive test results.
- Inadequate guidance on the criteria that will be applied in deciding whether a substance will be required to complete Tier II testing following the initial screen.

Final data submissions for the first 67 chemicals undergoing screening are not due until October 2011 (unless extensions are granted), and EPA is not likely to complete its evaluation of these Tier I data until sometime in 2012. Based on this schedule, EPA will not have an opportunity to apply "lessons learned" from the initial Tier I testing program as it finalizes its list of additional chemicals that will be subject to testing.

Please contact us if you have questions or concerns regarding applicability of compliance with EPA's notice.

Second EDSP List of Chemicals for Tier 1 Screening

Chemical Name	CAS Number
1,1,1,2-Tetrachloroethane	630-20-6
1,1,1-Trichloroethane	71-55-6
1,1,2-Trichloroethane	79-00-5
1,1-Dichloroethane	75-34-3
1,1-Dichloroethylene	75-35-4
1,2,3-Trichloropropane	96-18-4
1,2,4-Trichlorobenzene	120-82-1
1,2-Dibromo-3-chloropropane (DBCP)	96-12-8
1,2-Dichloroethane	107-06-2

Chemical Name	CAS Number
1,2-Dichloropropane	78-87-5
1,3-Dinitrobenzene	99-65-0
1,4-Dioxane	123-91-1
1-Butanol	71-36-3
2,4,5-TP (Silvex)	93-72-1
2-Methoxyethanol	109-86-4
2-Propen-1-ol	107-18-6
4,4'-Methylenedianiline	101-77-9
Acetaldehyde	75-07-0
Acetamide	60-35-5
Acetochlor	34256-82-1
Acetochlor ethanesulfonic acid (ESA)	187022-11-3
Acetochlor oxanilic acid (OA)	194992-44-4
Acrolein	107-02-8
Acrylamide	79-06-1
Alachlor	15972-60-8
Alachlor ethanesulfonic acid (ESA)	142363-53-9
Alachlor oxanilic acid (OA)	17 1262-17-2
alpha-Hexachlorocyclohexane	319-84-6

Aniline	62-53-3
Bensulide	741-58-2
Benzene	71-43-2
Benzo(a)pyrene (PAHs)	50-32-8

Chemical Name	CAS Number
Benzyl chloride	100-44-7
Butylated hydroxyanisole	25013-16-5
Carbon tetrachloride	56-23-5
Chlordane	57-74-9
Chlorobenzene	108-90-7
cis- 1 ,2-Dichloroethylene	156-59-2
Clethodim	99129-21-2
Clofentezine	74115-24-5
Clomazone	81777-89-1
Coumaphos	56-72-4
Cumene hydroperoxide	80-15-9
Cyanamide	420-04-2
Cyromazine	662 15-27-8
Dalapon	75-99-0
Denatonium saccharide	90823-38-4
Di(2-ethylhexyl) adipate	103-23-1
Dichloromethane	75-09-2
Dicrotophos	141-66-2
Dimethipin	55290-64-7
Dinoseb	88-85-7
Diuron	330-54-1
Endothall	145-73-3
Endrin	72-20-8

Chemical Name	CAS Number
Epichlorohydrin	106-89-8
Erythromycin	114-07-8
Ethylbenzene	100-41-4

Ethylene dibromide	106-93-4
Ethylene glycol	107-21-1
Ethylene thiourea	96-45-7
Ethylurethane	51-79-6
Etofenprox	80844-07-1
Fenamiphos	22224-92-6
Fenarimol	60168-88-9
Fenoxaprop-P-ethyl	71283-80-2
Fenoxycarb	72490-01-8
Flumetsulam	98967-40-9
Fomesafen sodium	108731-70-0
Fosetyl-Al (Aliette)	39148-24-8
Glufosinate ammonium	77182-82-2
HCFC-22	75-45-6
Heptachlor	76-44-8
Heptachlor epoxide	1024-57-3
Hexachlorobenzene	118-74-1
Hexachlorocyclopentadiene	77-47 -4
Hexane	110-54-3
Hexythiazox	78587-05-0

Chemical Name	CAS Number
Hydrazine	302-01-2
Isoxaben	82558-50-7
Lactofen	77501-63-4
Lindane	58-89-9
Methanol	67-56-1
Methoxychlor	72-43-5
Methyl tert-butyl ether	1634-04-4
Metolachlor ethanesulfonic acid (ESA)	171118-09-5
Metolachlor oxanilic acid (OA)	152019-73-3
Molinate	2212-67-1
Nitrobenzene	9 8-95-3
Nitroglycerin	5 5-63-0
N-Methyl-2-pyrrolidone	872-50-4

N-Nitrosodimethylamine (NDMA)	62-75-9
n-Propylbenzene	103-65-1
o-Dichlorobenzene	95-50-1
o-Toluidine	95-53-4
Oxirane, methyl-	75-56-9
Oxydemeton-methyl	301-12-2
Oxyfluorfen	42874-03-3
Paclobutrazol	7673 8-62-0
p-Dichlorobenzene	106-46-7
Pentachlorophenol	87-86-5

Chemical Name	CAS Number
Perchlorate	14797-73-0
Perfluorooctane sulfonic acid (PFOS)	1763 -23-1
Perfluorooctanoic acid (PFOA)	335-67-1
Picloram	1918-02-1
Polychlorinated biphenyls	1336-36-3
Profenofos	41198-08-7
Propetamphos	31218-83-4
Propionic acid	79-09-4
Pyridate	55512-33-9
Quinclorac	84087-01-4
Quinoline	91-22-5
Quizalofop-P-ethyl	100646-51-3
RDX	121-82-4
sec-Butylbenzene	135-98-8
Sodium tetrathiocarbonate	7345-69-9
Styrene	100-42-5
Sulfosate	81591-81-3
Temephos	3383-96-8
Terbufos	13071-79-9
Terbufos sulfone	56070-16-7
Tetrachloroethylene	127-18-4
Thiophanate-methyl	23564-05-8
Toluene diisocyanate	2647 1-62-5

Chemical Name	CAS Number
Toxaphene	8001-35-2
trans-1,2-Dichloroethylene	156-60-5
Trichloroethylene	79-01-6
Triethylamine	121-44-8
Triflumizole	68694-11-1
Trinexapac-ethyl	95266-40-3
Triphenyltin hydroxide (TPTH)	76-87-9
Vinclozolin	50471-44-8
Xylenes (total)	1330-20-7
Ziram	137-30-4

CAS Number = Chemical Abstract Services Registry Number

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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