

Date:

To: Business operators importing and/or manufacturing organic pigments

From: Director General of Manufacturing Industries Bureau, Ministry of Economy, Trade, and Industry

**Administrative Guidance for Manufacture/Import etc., of Organic Pigments Containing By-product PCBs**

Recently, there has been a report by the Japan Dyestuff and Industrial Chemicals Association (JDICA) that a certain type of organic pigments contains polychlorinated biphenyls (PCBs), one of Class I Specified Chemical Substances designated by the “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (hereinafter referred to as the “CSCL”).

Consequently, importers and/or manufacturers (hereafter referred to as the “business operators” are requested to confirm, based on the following provisions, whether any organic pigment manufactured and/or imported contains by-product PCBs.

This Administrative Guidance shall cover the organic pigments in which by-product PCBs were identified in the abovementioned report (Appendix 1) and shall be sent to the business operators who had notified the METI of their manufactured and/or imported quantity (regarding actual results from FY2010) in FY2011.

This is the beginning of a series of the Provisions

1. With regard to any Class I Specified Chemical Substance generated as a by-product during the manufacture of chemical substances, the CSCL is based on the standpoints that the generation of such a substance should be inhibited as much as possible. Under the CSCL, with an application of BAT (best available technology) rule, if a minute amount of a Class I Specified Chemical Substance are contained as a by-product and poses no risk of impairing human health or intervening with the inhabitation of growth of flora and fauna through the environmental pollution, and if the percentage of its content is considered to have decreased to a technically and economically feasible

level, such a by-product is not treated as a Class I Specified Chemical Substance. As indicated in the report by JDICA, certain types of organic pigments are likely to contain by-product PCBs that have been unintentionally generated in the course of their synthetic process etc. In response to this finding, the METI shall ask each respective business operator to confirm the content of by-products PCBs in the chemical substances that fall under any of the following provisions, by using the analysis methods provided in Appendix 2. Where by-product PCBs are detected, the business operator shall be asked to notify the MHLW, METI and MOE (hereinafter referred to as “the three Ministries”) of the fact as early as possible.

(1) For organic pigments reported by JDICA to contain PCBs at more than 0.5 ppm as listed in Appendix 1, relevant business operators shall confirm the content of by-product PCBs and report the result to the three Ministries as early as possible, but no later than May 10.

(2) For organic pigments other than those listed in Appendix 1, but meeting any of the following criteria shown by an overseas report [Position paper by ETAD (the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers) in January 2010, stating that PCBs may be unintentionally generated in the production process of certain types of organic pigments], relevant business operators shall confirm the content of by-product PCBs in such organic pigments and report the result to the three Ministries as early as possible, but no later than August 10:

- Pigments that contain chlorine as part of their molecular structure.
- Pigments that use chlorine-containing raw materials
- Pigments that use chlorine-containing solvents in their synthesis.

2. The three Ministries shall, for the time being, authorize the business operators who undertook reporting of Provision 1 to take the following measures:

(1) Where PCBs are detected at a level exceeding 0.005% (50 ppm), the threshold value under an international treaty (Stockholm Convention on POPs (Persistent Organic Pollutants)) at which the product is not allowed to be distributed in the global market(\*),

- The three Ministries shall provide the business operator with a direction to stop the manufacture or import and to suspend the use or shipment of the pigment, unless the administration has confirmed that appropriate measures have been taken to continuously reduce the level of PCBs in such pigment to be less than or equal to 50 ppm (tentative value) (which is defined as its reduction policy for the pigment).
- The three Ministries shall ask the business operator and the recipients to whom the former sent and delivered their pigment(s) in the past within a year, to swiftly report to the three Ministries the name and contact information of such recipients (the latter), the location where the pigment of concern was manufactured and/or imported or used.
- The three Ministries shall ask the business operator to collect the organic pigment of concern and properly keep the pigment until it is disposed off.

(2) Where the detected levels of PCBs are 0.005% (50 ppm) (tentative value) or lower,

- The three Ministries shall ask the business operator to establish the upper limit (self-imposed upper control limit) by themselves regarding the PCBs content in chemical substances based on the BAT rule and to give the explanation to the Ministries.

3. In addition, where it is found that, among clients with which the business operator directly or indirectly deals, any manufacturer/importer of organic pigments has not received this Administrative Guidance document yet, the manufacturer/importer shall be strongly encouraged to notify the three Ministries of such situation.

\* The technically and economically feasible level to which the content of by-product PCBs in an organic pigment can be reduced and the necessity for additional measures are intended to be reviewed by METI, MHLW and the MOE, in light of the actual situation, human health risks from PCBs, synthesis techniques of organic pigments, and regulatory developments in overseas, etc. In the future, the technically and economically feasible level of PCB content may be reduced to a level lower than the current tentative value.

(For your reference)

The purpose of the CSCL is to prevent environmental pollution due to any chemical substance being persistent, posing toxicity to human, and ecotoxicity. Class I Specified Chemical Substances are defined as those being persistent, highly bioaccumulative, and posing toxicity to humans or predator animals at higher trophic level. The CSCL has banned the Class I Specified Chemical Substances in principle, from being imported, manufactured, and used. In 1974, PCBs were designated as a Class I Specified Chemical Substance and have been subject to the related regulations under the CSCL. In addition, international efforts have been made to reduce PCB emissions based on the Stockholm Convention on POPs (persistent organic pollutants).

< Contacts for inquiries:○ : Ms.Nakagiri, Mr. Tsuno, and Ms.Hakojima  
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Appendix 1 Organic Pigments reported by JDCIA to contain by-product PCBs at more than 0.5 ppm

(1) Pigments where by-product PCBs were confirmed at a level exceeding 50 ppm

Names Published in Gazette
Pigment Red-2
Pigment Red-112

(2) Pigments where by-product PCBs were confirmed at a level exceeding 0.5 ppm less than 50 ppm

Names Published in Gazette
<ul style="list-style-type: none"> <li>• Pigment Yellow-87</li> <li>• Pigment Red-9</li> <li>• <math>\alpha</math>-(2,5-Dichlorophenylazo)-2-<math>\alpha</math>-acetylacetamide-6-ethoxybenzothiazole (Generic name: Pigment Yellow-165)</li> <li>• Pigment Brown-25</li> </ul>
<ul style="list-style-type: none"> <li>• 4,4'-Bis(acetoaceto-alchoxy (C = 1-4)anilide-2-yl-azo)-3,3'-dichlorodipheny (Generic name: Pigment Yellow-152)</li> <li>• 4,4'-Bis-[acetoacetyl-dialchoxy (C = 1-2)-anilide-2-yl-azo]-dichloro-dipheny (Generic name: Pigment Yellow-124)</li> <li>• Pigment Yellow-12</li> <li>• Pigment Yellow-13</li> <li>• Pigment Yellow-14</li> <li>• Pigment Yellow-17</li> <li>• Pigment Yellow-55</li> <li>• Pigment Yellow-81</li> <li>• Pigment Yellow-83</li> <li>• Pigment Orange-13</li> <li>• Pigment Orange-16</li> <li>• Pigment Red-38</li> </ul>
<ul style="list-style-type: none"> <li>• Pigment Violet-23</li> </ul>
<ul style="list-style-type: none"> <li>• Pigment Green-7</li> <li>• Pigment Green-36</li> <li>• Mixture of phthalocyaninato zinc(II) bromide and phthalocyaninato zinc(II) bromide/chloride (which is the product of a ring substitution reaction and contains at least four bromine elements)</li> </ul>

(Generic name: Pigment Green-58)
· 3,6-Bis-(4-chlorophenyl)pyrrolo[3,4-c] pyrrole-1,4(2H, 5H)-dione
(Generic name: Pigment Red-254)

## Appendix 2 Analysis Methods

Preferable methods are as follows—Accurately weigh the sample and dissolve with sulfuric acid to maintain a constant volume. After that, extract PCBs from the solution with a solvent such as hexane, followed by determination of the PCBs content using, for example, GC/ECD (gas chromatography/electron capture detection) or GC/MS (gas chromatography/mass spectrometry). Preferably, the detection limit should be set to about 0.1 ppm so that PCBs in the organic pigment can be quickly detected even in trace amounts.

Appendix 2-2

Date:

To: Related business operators

From: Director General of Manufacturing Industries Bureau, METI

**Administrative Guidance for Manufacture/Import etc., of Organic Pigments  
Containing By-product PCBs**

Recently, there has been a report by Japan Dyestuff and Industrial Chemicals Association (JDICA) that a certain type of organic pigments contains polychlorinated biphenyls (PCBs), one of Class I Specified Chemical Substances designated by the “Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (hereinafter referred to as the “CSCL”).

In response to the report, business operators who have notified the METI of their manufactured and/or imported quantity (regarding actual results from FY2010) in FY2011 are requested to confirm as provided in Appendix2-1, regarding such organic pigments containing by-product PCBs as listed in the JDICA report.

This notification (Administrative Guidance) shall be sent to the business operators other than above-stated business operators who have notified the METI of their manufactured and/or imported quantity in FY2011. Related business operators shall be requested to confirm, based on Appendix2-1, if you manufactured and/or imported any organic pigment by your business.

< Contact for inquiries >

○Ms.Nakagiri, Mr.Tsuno, and Ms.Hakojima

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\* Appendix2-1 shall be attached.



February 10, 2012

To: Mr. Koji Takahashi, the President of Dainichiseika Color & Chemicals Mfg. Co., Ltd.

From: Director of the Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW;

Director of the Chemical Management Policy Division of Manufacturing Industries Bureau, METI; and

Director of the Policy Planning Division of Environmental Health Department, Environmental Policy Bureau, MOE

**Manufacture/Import etc., of Pigment Red-2 (Administrative Guidance)**

Since there is a high possibility that the chemical substance described in the following Provision 1 contains polychlorinated biphenyls (PCBs), one of Class I Specified Chemical Substances designated by the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc., (CSCL) and that, in that case, the content of PCBs does not be considered to be minute amounts, your business shall be requested to take appropriate measures as shown in Provision 2 below.

This is the beginning of a series of the Provisions

1. Target Chemical Substance

Substance Name in the Gazette List: Pigment Red-2, Pigment Red-112

2. Measures Requested to be Taken

(1) The abovestated business operator shall be asked to stop the manufacture or import as well as to suspend the use or shipment of the chemical substance described in the above Provision 1 unless the administration has confirmed that appropriate measures have been taken to continuously reduce the level of PCBs in such pigment to be less than or equal to 50 ppm(\*). However, this shall not be applicable to a production lot where chemical analysis has confirmed that the content of PCBs is not more than 50 ppm.

(2) The abovestated business operator shall be asked to report to the three Ministries the location where the chemical substance described in the above Provision 1 was manufactured and/or imported or used. In addition, such a business operator shall be also asked to swiftly report to the same Ministries the name and contact person of other business operator to whom the former sent and delivered its chemical substance in the past within three years as well as the usage of the chemical substance and the location where the substance was used.

However, this shall not be applicable to a production lot where chemical analysis has confirmed that the content of PCBs is not more than 50 ppm.

(3) If there are any chemical substances described in the above Provision 1 that are unused and have been currently maintained at the premise of the business operator to which it was sent, such chemical substances shall be collected as early as possible.

\* Not only the technically and economically feasible level to which the content of by-product PCBs in an organic pigment can be reduced but also the necessity for additional measures are intended to be reviewed by both the MHLW, the METI, and the MOE, in light of a research on the actual situation, human health risks from PCBs, synthesis techniques of organic pigments, trends in overseas regulations, etc., and may become lower than the current value in the future.