

March 4, 2016

To All Parties Concerned

Office of Chemical Safety, Pharmaceutical Evaluation Division, Pharmaceutical Safety and
Environmental Health Bureau, Ministry of Health, Labour and Welfare
Chemical Safety Office, Chemical Management Policy Division, Manufacturing Industries
Bureau, Ministry of Economy, Trade and Industry
Chemicals Evaluation Office, Policy Planning Division, Environmental Health Department,
Environmental Policy Bureau, Ministry of the Environment

Handling of Chemical Substances Containing By-Product Class I Specified Chemical Substances
(Notification)

In the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Act No. 117 of 1973, referred to as the “Chemical Substances Control Law” below), the “Best Available Technology/Techniques (BAT)” principle is applied to Class I Specified Chemical Substances¹ that are generated as a By-Product when manufacturing other chemical substances. On the basis of an approach of reducing Class I Specified Chemical Substances to a “technically and economically feasible level”, it is established in the “Implementation of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.” (March 31, 2011, Pharmaceutical and Food Safety Bureau No. 0331, Item No. 5; March 29, 2011, Manufacturing Industries Bureau, Item No. 3, Environmental Policy Bureau Item No. 110331007; referred to as “Implementation Notifications” below) that if such By-Product poses no risk of impairing human health through environmental pollution caused by By-Product Class I Specified Chemical Substances, and it is recognized that its content is reduced to a technically and economically feasible level, the By-Product substance is not handled as Class I Specified Chemical Substances (refer to Implementation Notification 3-3).

Furthermore, these details are determined in the “Handling of Chemical Substances Containing By-Product Class I Specified Chemical Substances (Notification)” (December 26, 2008; referred to as the “2008 Notification” below), and implementations have been carried out based on this notification.

Here, with the compilation of the “Report on a Technically and Economically Feasible Level for Reduction of the Content of By-Product PCBs in Organic Pigments” (January 29, 2016), the handling of By-Product Class I Specified Chemical Substances and chemical substances containing these in small quantities is revised as follows.

Note that the 2008 Notification is to be discontinued with the publication of this notification.

¹Class I Specified Chemical Substances: chemical substances whose manufacture, import and use are generally prohibited

SUMMARY

Operations of By-Product Class I Specified Chemical Substances are currently carried out based on Implementation Notification 3-3, and from now they are to be handled as follows.

1. When By-Product Class I Specified Chemical Substances are recognized as being contained in chemical substances in small quantities, the following measures should be taken as soon as possible. When these measures are adequate, they are deemed applicable under Implementation Notification 3-3.

(1) If chemical substances containing By-Product Class I Specified Chemical Substances in small quantities are manufactured or imported after recognition of this fact, the operator itself is to set an upper limit with respect to the content of the Class I Specified Chemical Substances within the chemical substances based on the BAT principle (referred to as a “self-managed upper limit value” below), and submit documentation to the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, and the Ministry of the Environment (referred to as the “three Ministries” below) together with the reduction measures of the relevant contained Class I Specified Chemical Substances, explaining the validity thereof.

(2) An operator that has set self-managed upper limit value and submitted documentation to the three Ministries (including operators that have set self-managed upper limit value and submitted documentation to the three Ministries in accordance with 1. (1)) is to consistently confirm that the Class I Specified Chemical Substances content within chemical substances the operator manufactures or imports does not exceed the self-managed upper limit value, and endeavor to continue reducing this content. Consequently, the self-managed upper limit submitted to the three Ministries is to be reported with respect to its management conditions in response to requests by the three Ministries, and to be appropriately revised according to changes in the conditions.

2. Tetrachlorophthalic anhydride (referred to as “TCPA” below), pigments or dyes having TCPA as a raw material (referred to as “TCPA-derived pigments” below), and pigments or dyes manufactured by chlorinating Pigment Blue 15 (referred to as “phthalocyanine pigments” below) are generally recognized as containing small quantities of hexachlorobenzene (referred to as “HCB” below) generated as By-Products, and thus the following measures from the initiatives to date based on “Handling of Pigments Containing By-Product Hexachlorobenzene Associated with the Revision of ‘Implementation of the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.’ (Notification)” (October 15, 2007; referred to as the “2007 Notification” below) are to be continued.

(1) If TCPA, TCPA-derived pigments and phthalocyanine pigments are newly manufactured or imported, the By-Product HCB content is to be confirmed and the self-managed upper limit that is intended to be set is to be submitted beforehand to the three Ministries, explaining the validity

thereof.

However, if the self-managed upper limit values pertaining to TCPA, TCPA-derived pigments (excluding Pigment Yellow 138) and Pigment Green 36 (a type of phthalocyanine-type pigment) exceeds the standard HCB content levels presented in the 2007 Notification (see below), as a general rule, the HCB generated as By-Products are deemed not to be applicable under Implementation Notification 3-3.

Note that if there is a change in conditions that would present an impediment to the supply of TCPA, or in cases where other TCPA-derived pigments and phthalocyanine pigments are to be manufactured or imported as new chemical substances, it is possible to apply self-managed upper limit values other than the standard levels below based on the BAT principle upon consideration of each individual situation.

[Standard By-Product HCB content levels]

- 1 TCPA: 200 ppm
- 2 TCPA-derived pigments (excluding Pigment Yellow 138): 10 ppm
- 3 Pigment Green 36: 10 ppm

(2) An operator that has set self-managed upper limit value and submitted documentation to the three Ministries (including operators that have set self-managed upper limit value and submitted documentation to the three Ministries in accordance with 2. (1)) is to consistently confirm that the HCB content within chemical substances the operator manufactures or imports does not exceed the self-managed upper limit value, and is to compile each calendar year various data for every lot (analysis results, date manufactured/imported, quantity manufactured or imported, and purpose), and report them to the three Ministries by the end of March of the following year.

However, TCPA, TCPA-derived pigments (excluding Pigment Yellow 138), and Pigment Green 36 are such that, as noted in 2. (1), the By-Product HCB content does not exceed the corresponding standard levels except in special cases, and thus periodic reporting to the three Ministries is not necessary.

3. Some organic pigments are generally recognized as containing small quantities of PCB generated as a By-Product, and thus the following measures are to be taken.

(1) If organic pigments satisfying any of the following conditions are to be manufactured or imported (including cases where they have already been manufactured or imported), the By-Product PCB content is to be confirmed, and the self-managed upper limit value representing the standard by which the operator decides whether to proceed with shipping, and the management method including the analysis method and the analysis frequency, are to be reported beforehand to the three Ministries, explaining the validity thereof. If manufacturing or importing has already been carried out,

reporting is required by December 2016.

- Pigments that contain chlorine atoms in their chemical structure
- Pigments that use raw materials containing chlorine atoms
- Pigments that use chlorinated aromatic solvents in their synthetic process

However, the self-managed upper limit value is to be set to a low level of 50 ppm or less, which is considered to be the concentration at which international distribution is avoided, and within a range that is technically and economically achievable in industry.

(2) An operator that has set a self-managed upper limit value is to consistently confirm that the PCB content concentration within chemical substances the operator manufactures or imports does not exceed the self-managed upper limit value, and is to compile various data such as manufacturing/import records and analysis results, and the status of investigations with respect to PCB reduction measures each calendar year, and report them to the three Ministries by March of the following year. This reporting is going to commence from the year 2017 (the first reporting to the three Ministries for the year 2017 is going to occur between January and March of 2018). Note that various data such as manufacturing/import records and analysis results are to be appropriately managed such that they can be submitted in response to requests by the three Ministries.

If the PCB content concentration exceeds the self-managed upper limit value, as a general rule, it is deemed not applicable under Implementation Notification 3-3, and thus immediate reporting to the three Ministries is required at the time the PCB content concentration exceeding the self-managed upper limit value is detected.

(3) When either of the following are applicable, periodic reporting as noted in 3. (2) is unnecessary for the time being.

- 1 When the self-managed upper limit value is reported as being 10 ppm or less in 3. (1), and management to the self-managed upper limit value or lower is being carried out
- 2 The self-managed upper limit value is set higher than 10 ppm, but the management is such that an upper limit value representing an in-house target for management to a level lower than the self-managed upper limit value (referred to as an “in-house standard value” below) is set to 10 ppm or less, and it has already been reported in 3. (1) that in-house management is being carried out such that the value is not exceeded, and management to be the in-house standard value or lower is being carried out

However, reporting requests from the three Ministries are not limited to the above, so various data such as manufacturing/import records and analysis results are to be appropriately managed.

Furthermore, with regard to 2, cases where values are detected that is within the self-managed upper limit value but in excess of the in-house standard value, they are subject to periodic reporting according to 3.(2) from that year onward.