Message

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Sent: 7/23/2019 1:36:57 PM
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Subject: RE: Recent Regulatory Developments: China in Talks to Join the OECD System for Mutual Acceptance of Data in Assessment of Chemicals

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The article is five years old.

Any update?

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From: Doroski, Brenda
Sent: Tuesday, July 23, 2019 7:51 AM
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Subject: FW: Recent Regulatory Developments: China in Talks to Join the OECD System for Mutual Acceptance of Data in Assessment of Chemicals

Forwarding article from Steve Wolfson, OGC related to yesterday's meeting on China GLP.

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From: Wolfson, Steve
Sent: Thursday, July 18, 2019 12:27 PM
To: Doroski, Brenda <Doroski.Brenda@epa.gov>
Subject: Recent Regulatory Developments | Bergeson & Campbell

FYI -

https://www.lawbc.com/index.php/regulatory-developments/entry/china-in-talks-to-join-the-oecd-system-for-the-mutual-acceptance-of-data-in

Regulatory Developments

China in Talks to Join the OECD System for the Mutual Acceptance of Data in Assessment of Chemicals

July 2, 2014

It has recently been reported that China is in discussions with the Organization for Economic Cooperation and Development (OECD) to become a provisional adherent to the Mutual Acceptance of Data (MAD) system. This would require China to accept data from safety testing of chemicals from participating countries generated under the MAD conditions and to establish a Good Laboratory Practice (GLP) compliance monitoring program. If China were to become a provisional adherent to the MAD system, this decision could conflict with its requirement that certain environmental and aquatic toxicity studies be conducted in China. The timeframe for the discussions was not provided.

Background

China has been following developments on the MAD system and GLP Principles of the OECD since 2003 and promoting GLP for adhering to the MAD system since its first participation in the annual meetings of the OECD Working Group on GLP as an *ad hoc* observer in 2005. The Chinese delegation reported the progress on implementing GLP in China and expressed its interest in adhering to the MAD system at the 22nd meeting of the OECD Working Group on GLP in 2008. In the same year, the Certification and Accreditation Administration of China (CNCA) issued a series of GLP-related regulations and guidance documents in line with the MAD requirements, which became effective on April 1, 2009, and the laboratory accreditation body of China, China National Accreditation Service for Conformity Assessment (CNAS), included the GLP accreditation into its evaluation system.

The OECD MAD Program

The OECD MAD system is implemented through a series of OECD Council Decisions that are legally binding on OECD member countries. MAD is primarily intended to facilitate a harmonized approach to

the development of "mutually acceptable" test data on chemicals and pesticides, and thereby reduce expensive and duplicative testing, eliminate country-specific testing requirements as a non-tariff trade barrier, and lower the cost to industry of meeting regulatory requirements on chemicals and pesticides. The MAD system also enables information sharing among governments and industry with respect to the results of various health and safety and environmental tests done on chemicals and pesticides. Participation in the MAD system requires that testing be carried out using OECD test methods (known as OECD Test Guidelines) and data quality procedures (known as OECD GLP Principles). Governments verify laboratory compliance using OECD procedures.

The first step towards participation in the MAD system by non-member countries is provisional adherence. During this time, non-members work with OECD countries to make their compliance monitoring program on GLP acceptable to all members. Provisional adherence to the OECD system means that the non-member must accept data from OECD member countries and other adhering countries generated under the MAD conditions. GLP monitoring activities in the provisional adherence country do not have to be accepted by the full adherents during the period of provisional adherence. A provisional adherent can become a full adherent after expert teams from three OECD governments have evaluated and approved its GLP compliance monitoring program on-site, the country has been determined by OECD to have fully implemented the MAD Council Decisions, and the country has been invited by the OECD Council to adhere to the Decisions and to join the OECD's MAD Program as a full member with the same rights and obligations as member countries.

To date, the mutual recognition of safety assessment data has materialized among 40 countries, including OECD's 34 members and six non-OECD countries (Argentina, Brazil, India, Malaysia, Singapore, and South Africa) under the MAD system. Thailand is a provisional adherent to the MAD system.

Benefits of the OECD MAD Program

MAD has been recognized and accepted since 1981 as the foundation for OECD's work on testing, assessment, and control of chemicals and pesticides. Through its efforts to ensure that testing conducted in accordance with OECD test guidelines and GLPs "shall be accepted" for review by OECD member countries and adherent countries, OECD is estimated to have saved government and industry €150 million (or about $200 million) per year ("Cutting Costs in Chemicals Management: How OECD Helps Governments and Industry" (2010)). Other significant non-monetary benefits of MAD include:

- Avoidance of non-tariff barriers to trade created by differing test methods required by various countries.

- Reduction in the use and suffering of laboratory animals needed for toxicological tests as fewer tests are required and as OECD has developed more humane test methods.

- Ensuring a level playing field for industry by establishing consistent methodological and quality requirements for testing conducted in OECD and adhering countries.

Current GLP Status of China

The establishment of the GLP system in China has significantly progressed over the past decade by joining forces with the Chinese Ministry of Environmental Protection (MEP, formerly SEPA), the Ministry of Agriculture (MoA), the China Food and Drug Administration (CFDA, formerly SFDA under the Ministry of Health), and the Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ). The CNCA was created under the AQSIQ with the approval of the China State Council in 2001, which granted the CNCA the mandate to manage, oversee, and coordinate the certification and accreditation of laboratories and inspection institutes nationwide. The CNAS was authorized to be the laboratory accreditation body by the CNCA. As the authority for the qualifications of laboratories in China, the CNCA has been working for an incorporation of the GLP program of China into the framework of the MAD system.

In the past decade, several series of GLP-related regulations and guidance documents were issued in China, which include *Good Laboratory Practices for Non-Clinical Studies of Pharmaceuticals* by the CFDA in 2003, *Good Laboratory Practices for Toxicity Studies of Pesticides* (NY/T 718-2003) and *Good Laboratory Practices for Physical and Chemical Testing of Pesticides* (NY/T 1386-2007) by the MoA in 2003 and 2007, respectively, *The Guidelines of Chemical Testing Good Laboratory Practices* (HJ/T 155-2004) by the MEP in 2004, and *Principles of Good Laboratory Practice* by the AQSIQ in 2008. The GLP guidelines issued by MEP and AQSIQ are in line with the MAD requirements and GLP Principles of OECD, while the GLP guidelines issued by CFDA and MoA are also used GLP standards of the United States Food and Drug Administration (FDA) and Japan as their references.

China has translated and published the Chinese version of *OECD Guidelines for the Testing of Chemicals* in August 2013. *The Guidelines for the Testing of Chemicals* of China was initially published by the MEP Chemical Registration Center (CRC) in 2004, which was revised and published in September 2013. In the 2nd edition of *The Guidelines for the Testing of Chemicals*, there are four volumes, including *Physical Chemical Properties and Physical Hazards; Effects of Biology Systems; Degradation and Accumulation*; and *Health Effects* with a total of 186 test methods.

Many GLP inspectors from the United States and OECD countries have been invited to convene on-site training courses for Chinese GLP inspectors and technicians from test facilities since 2005. Some Chinese inspectors have also been invited to participate in several GLP inspections conducted by OECD inspectors as observers. To date, 57 test facilities have received the GLP certification of CFDA for non-clinical studies of pharmaceuticals, 11 test facilities qualified for eco-toxicological tests for

new chemical substances notification by the MEP, six test facilities passed GLP qualification inspection for safety evaluation of pesticides and veterinary drugs by the MoA, and seven test facilities received the GLP certification of CNAS for evaluation of industrial chemicals in China. Additionally, several test facilities in China received GLP certification from the GLP monitoring authority of OECD member countries. In 2011 alone, five Chinese test facilities received full GLP inspection and certification by the Belgian GLP Program.

Although a Chinese test facility can be found in compliance after an inspection from the GLP monitoring authority of an OECD member country, this is not a guarantee for the test facility that the data will be accepted by the OECD member countries because China is not yet an adherent to the MAD system. Each receiving authority may decide to send additional GLP inspectors to verify the accuracy of their compliance status for a specific study.

Commentary

It would be a significant development if China completes the path to full MAD adherence, which would establish a legal obligation for Chinese regulatory authorities to accept testing conducted in accordance with MAD, including testing conducted in OECD and adherent countries. To the extent that this requirement is fully accepted and implemented in China, it would help to "level the playing field" between international industry and the Chinese domestic industry by presumably changing requirements that certain environmental and aquatic toxicity testing must be conducted in Chinese laboratories, a requirement that can impose additional costs on international companies. The change could also inspire new business development in China as China-specific data could be replaced by data developed in other jurisdictions. It will be important to follow China's progress in the coming years in moving toward its possible acceptance as an OECD MAD provisional adherent country, and potentially thereafter as a full adherent to MAD.