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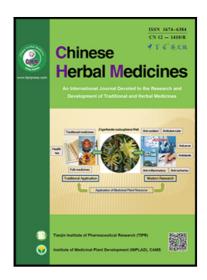
Cong-min Liu , Jia-an Qin , Xiao-wen Dou , Mei-hua Yan g , Xiao-bo Sun

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#### ACCEPTED MANUSCRIPT

# Extrinsic harmful residues in Chinese herbal medicines: types, detection and safety evaluation

Cong-min Liu 1, Jia-an Qin 1, Xiao-wen Dou, Mei-hua Yang \*, Xiao-bo Sun\*

Key Laboratory of Bioactive Substances and Resources Utilization of Chinese Herbal Medicines, Ministry of Education, Institute of Medicinal Plant Development, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing 100193, China.

Abstract: Chinese herbal medicines (CHMs) are playing important roles in the treatment of diseases and human health care throughout the world. However the extrinsic harmful residues have been threatening the therapies by destroying CHMs qualtiy which hinders the international trades of CHMs. This review summarized the extrinsic harmful residues contaminating CHMs in types, detection methods, national and international regulations, and made safety evaluations according to their contaminated levels, aiming to establish understanding among nations or organizations and provide references for the formulation or amendment of relative regulations.

Keywords: Chinese herbal medicines; extrinsic harmful residues; limit standards; monitor; regulations

#### 1. Introduction

Nowadays, Chinese herbal medicines (CHMs) have been increasingly accepted worldwide for their unique curative effects, rich resources, less toxic and side effects, playing an important role in protecting human health. However, as the increase in the demand of CHMs, many issues on the safety and quality of CHMs have gained the increasing concerns. There are many reports about the international trade obstacles of CHMs in recent years, mainly on the case of excessive levels of extrinsic harmful residues in CHMs including mycotoxins, pesticides, heavy metals and sulfites. They are contaminating CHMs in many ways, such as the environmental pollution, the improper storage or processing, and the artificial interference during the cultivation of medicinal plants.

Considering the potential hazards they caused on CHMs, many countries or organizations have formulated relative provisions, such as the "WHO Guidelines for Assessing the Quality of Herbal Medicines with Reference to Contaminants and Residues" (WHO, 2007) to promote the quality control of CHMs and ensure the safety and efficacy of the use of CHMs. These provisions promoted the requirement of CHMs and increased the technical barriers of the trades of CHMs on the contrary. For example, the amendment of the "Specification and Test Method for Heavy Metals/Residual Sulphur Dioxide in Herbal Medicines" by Korea (G/TBT/N/KOR/154, 2007; G/TBT/N/KOR/158, 2007), covering most of the varieties of CHMs exported from China, had once

greatly increased the difficulty of the trade of CHMs. In 2016, the top ten exported CHMs in China were detained or returned 18 times by Japan, the United States, the European Union, South Korea, and many other countries because of the issues of extrinsic harmful residues. Although it represented a better situation compared with the 30 times in 2015, the problems of extrinsic harmful residues are still serious and have become a stumbling block that limits the development and international trades of CHMs.

Different from the active ingredients in CHMs, the extrinsic harmful residues have some special characteristics (Ma et al, 2015). Most extrinsic harmful residues hardly have acute toxicity but with accumulative and concealed toxicity. They are more difficult to be detected than the bioactive compounds in CHMs due to the trace level, so that complex technology and high cost are needed. Furthermore, as the varieties of CHMs and extrinsic contaminants, there haven't been unified limit standards for the extrinsic harmful residues around the world, leading to trade barrier of CHMs.

Based on the mycotoxins, pesticides, heavy metals and sulfites, this review summarized their potential harm, limit standards, detection methods, and current contaminated situation on CHMs, aiming to eliminate the public misunderstanding or panic, provide reference for the formulation or amendment of relative regulations, and promote the healthy and stable development of CHMs (Figure 1).

\_\_\_\_Figure

#### 1\_

#### 2. Mycotoxins

#### 2.1 Production, species and harm of mycotoxins

Mycotoxins are secondary metabolites produced by the toxic fungi in the appropriate environmental conditions (Bennett and Klich, 2003) that extensively pollute crops, food, feed, CHMs and other herbal products. Fungus are multicellular microorganisms that spread by seeds or spores widely in air, water, soil and other natural environments, leading to herb infection (Bugno et al, 2006; Romagnoli et al,

2007). The germination and reproduction of fungal spores on the CHMs degraded the chemical composition of CHMs, destroying efficacy and quality of CHMs. As herbal products, CHMs are susceptible to fungi and mycotoxins from multiaspects, such as the field, processing, storage, transportation, and even the users of the CHMs (Li and Li, 2011), increasingly and extensively concerned around the world recent years. The toxic fungi mainly include Aspergillus, Penicillium, Fusarium, Alternaria,

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