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Tel. direct: Fax direct: E-mail: In reply please refer to:

Your reference:

Saerfu (Henan) Agrochemical Co., Ltd Mr Hai yong Li Room 810, AS1 Building Baolong Plaza Wenquan Rd 271000 Taian Republique Populaire de Chine

03 September 2019

Dear Mr Li,

# WHO Prequalification Team – Vector Control VCP Prequalification – Letter of Prequalification

Product number: 035-001

Thank you for submitting the information requested and for your voluntary participation in this procedure for conversion. Your application for conversion, submitted on 7 August 2019, and preceding letter provided an explanation for your request for conversion despite the completion of the Conversion Process on 30 April 2018. Your submission to WHO and request for inclusion in the JMPS procedures for the extension of an established specification to include this product was completed as part of the 2018 JMPS meeting in June of 2018. Given the status of your application during the Conversion Process, the timing of the JMPS meeting, and the positive outcome, it was determined that your conversion application could be accepted.

The review of your company's application for conversion of:

#### • 035-001 - FastM

has been completed and it has been found to meet the criteria for conversion to Prequalification and is acceptable, in principle, for procurement by United Nations and other international agencies and countries.

This conclusion is based on information available to the World Health Organization at the current time, i.e. the information in the application for conversion and previous evaluations/reports. Please note, however, that this decision may change based on new information that may become available. Therefore, the product will now be included on the list of vector control products, which are considered to be acceptable, in principle, for procurement by UN organizations. This list is published by WHO at http://www.who.int/pq-vector-control/prequalified-lists/en/.

Please note that inclusion on the list cannot be construed as WHO approval or endorsement, and does not necessarily mean that the listed products will actually be procured from the suppliers mentioned. The list, and the WHO name, emblem and/or acronym may not, furthermore, be used by the applicants, manufacturers, suppliers or any other parties for commercial or promotional purposes.

ENCL: (1)

The applicants and the manufacturers of prequalified products are required to communicate to WHO details of any changes in manufacture or control that may have an impact on the safety, efficacy and/or quality of the product.

Finally, I should like to draw your attention to the fact that the list will be reviewed and updated at regular intervals. Consequently, WHO could, at regular intervals, arrange for the products included on the list to be re-evaluated.

Yours sincerely,

Marion Law

Group Lead, Vector Control Products

Prequalification Team

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Regulation of Medicines and other Health Technologies

## **Statement of Conversion to Prequalification**

#### **Criteria for Conversion**

For those manufacturers of vector control products who wish to have their product(s) considered for prequalification based on a previous recommendation by WHO, an application for conversion is required to be submitted.

All applications for conversion are screened for completeness and the products are reviewed to ensure supporting WHO safety and efficacy evaluations and specifications are available.

In cases of country-level major regulatory actions (for example, cancellation of registrations/uses) in regards to an active ingredient, WHO may require additional analysis prior to conversion of any associated products.

### **Description of Product**

PQT-VC Product Reference Number	035-001
Product Name	FastM
Intervention Type	IRS
Applicant	Saerfu (Henan) Agrochemical Co., Ltd
Active Ingredient	Bendiocarb
AI Concentration	80% (800 g/kg)
Formulation Type	WP-SB
Equivalent	Ficam; PQT-VC Ref 008-005

#### **Statement of Review**

An application for conversion of the product **FastM** was submitted by **Saerfu (Henan) Agrochemical Co., Ltd** on **7/8/19**. The application was deemed to be complete for the purposes of conversion.

Upon review of the product it was determined that the submitted product is supported by WHO evaluations for safety and efficacy. The WHO specification identified by the applicant was verified and found to be applicable to the product submitted for conversion.