



Contents lists available at ScienceDirect

Journal of Applied Research on Medicinal and Aromatic Plants

journal homepage: www.elsevier.com/locate/jarmap

Letter to the editor

EUROPAM statement on requirements for a batch certification of medicinal and aromatic plants (MAPs)



Today, a difficulty in everyday business life of MAP production is that most customers demand batch certificates containing information they consider important and issued in their proprietary forms leading to a multitude of different forms and complexity. When a batch is transferred from a producer/trader to a customer, information (a certificate) has to be attached providing information about the product, guaranteeing traceability, allowing a first risk assessment and certifying compliance to certain regulations (e.g. GACP). However, it should not be too complex in order to keep the business process administrable. It is thus necessary to find a good compromise between a comprehensive and a short batch certificate.

Both developments, extensive demand for information and a multitude of proprietary customer questionnaires bind a lot of working hours on the producers' and/or traders' side leading to inefficiencies in production or trade and often to disappointments in the seller/buyer relationship. Therefore EUROPAM proposes a defined format for a batch certificate (Table 1) that includes all reasonable information about a batch in order to harmonize and simplify batch certification in a similar way as now obligatory for medicinal products (EMA, 2011).

Good agricultural and wild collection practice of MAPs (GACP) (EMA, 2005; EUROPAM, 2010) is a guideline for quality management including information collection and management during the production process. A batch certificate is not a complete collection of all GACP-compliant data, but should contain that part of information that (1) defines the batch (batch number, etc.), (2) influences the business process (e.g. conventional or organic production), (3) allows a fast risk assessment (e.g. pesticides used) and (4) guarantees compliance with specific regulations (e.g. permits for wild collection, GACP compliance). Access to additional data should be a matter of bilateral agreements beyond a batch certificate.

1. Explanatory notes and glossary

1. General information: A batch needs a description identifying the content of the batch (the commercial and scientific name, the plant part, supplier, batch number and

quantity transferred). Besides the commercial trade name, the scientific name is essential for MAPs.

Additionally, it is important to know about the mode of production and origin of the product (cultivation or wild collection, conventional or organic production, geographical origin and harvest period). In case of wild collection, it is also essential for the customer to immediately know if a collection permit was required.

2. Cultivation: From cultivation data, risk-related parameters are of primary importance. They can be limited to the three parameters: irrigation, fertilization and agrochemicals (plant protection products) (Damalas and Eleftherohorinos, 2011).

3. Post-harvest processing: Requested, if at least one of the following processes was applied: 'Washing', 'Freezing', 'Cutting', 'Distillation', 'Steam treatment', 'Irradiation', 'Drying', 'Fumigation' and 'Separation'. More details are important for the specifically risk-related processes drying (natural or artificial drying and the type of fuel used in case of direct artificial heating) and fumigation (fumigant) (Purcaro et al., 2013). Since the separation processes may be rather diverse, a list of all applied separation processes applied shall be given. Processes applied but not listed have to be declared ('Others'). 'Packaging material' and 'Storage conditions' have to be included in the batch certificate because of their impact on quality.

'GACP-compliance': For sectors where the EMA/HMPC guideline is not valid (e.g. the food sector) the option 'not applicable' is given. The following text should be used: 'I hereby certify that the above information is authentic and accurate. This batch has been produced at the above mentioned sites in full compliance with the EMA GACP Guidelines (EMA/HMPC/246816/2005). The batch processing records were reviewed and found to be in compliance with GACP.'

2. Summary

A production batch needs a comprehensive but administrable certificate. In the area of medicinal and aromatic plant production, such a document should not only contain a unique batch number and general information but also questions that are risk-related or related to legal requirements. The European Herb Growers Association (EUROPAM) proposes such a comprehensive but short batch certificate in order to simplify and

Table 1

Proposed content of a batch certificate for medicinal and aromatic plants.

1. General information
1.01. Product (commercial name)
1.02. Species (scientific name)
1.03. Plant part
1.04. Supplier
1.05. Batch number
1.06. Quantity
1.07. Cultivation or wild collection (if wild collection: permit required?)
1.08. Conventional or organic production
1.09. Origin (country and district)
1.10. Harvest year and harvest period
2. Cultivation
2.01. Irrigation (yes/no)
2.02. Fertilization (none/mineral/organic)
2.03. Plant protection products used (trade name/active substance)
3. Post-harvest processing
3.01. Washing (yes/no)
3.02. Freezing (yes/no)
3.03. Cutting (yes/no)
3.04. Distillation (yes/no)
3.05. Steam treatment (yes/no)
3.06. Irradiation (yes/no)
3.07. Drying (natural/artificial), if artificial name of combustible (direct heating only)
3.08. Fumigation (yes/no), if yes fumigant used
3.09. Separation procedures
3.10. Other post-harvest procedures
3.11. Packaging material
3.12. Storage conditions
4. Other comments
5. Compliance
5.1. Production in compliance with GACP according to EMEA/HMPC/246816/2005? (yes/no/not applicable)
5.2. Name and position/title of person authorizing the batch release
5.3. Signature of person authorizing the batch release
5.4. Date of signature

harmonize batch certification in raw material supply of MAPs.

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Glossary

Batch: A batch (synonym: lot) is a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous (European Commission, 2011).

Batch Number: A batch number (=lot number) is a unique combination of numbers, letters or symbols that identifies a batch and from which the production and distribution history can be determined (European Commission, 2011).

GACP: abbrev. 'Good Agricultural and Collection Practice'.

MAP: abbrev. 'Medicinal and Aromatic Plants'.

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Received 22 April 2014

Accepted 19 May 2014

Available online 8 August 2014