



Analysis of monacolins in food supplements and ingredients

Monacolins are described as polyketides that are secondary metabolites produced by the fermentation of red rice with the fungus *M. purpureus*, where the most abundant is monacolin K⁽¹⁾. Monacolin K in lactone form is basically identical to lovastatin's, a statin used in the pharmaceutical industry to lower blood cholesterol levels⁽²⁾.

Red yeast rice (RYR) is traditionally used in China as a food colouring and as a traditional remedy to promote digestion and blood circulation. In the EU, it is not authorised for use as a food colour as it is not included in the EU list of Regulation (EC) No 1333/2008 on food additives. Food supplements containing red yeast rice preparations **have been marketed and consumed for a long time and to a significant degree.**

The issue of RYR

Despite its low dosage in food supplements, the presence of monacolin K (sharing the well-known adverse effects of statins and varying levels of the other monacolins whose **safety has not been established**), **exposes some consumers to a health risk** that need to be evaluate by the Authorities.

The rules on food supplements

Following the scientific opinion on the safety consumption of monacolins in red yeast rice (RYR) delivered by the Panel on Food Additives and Nutrient Sources added to Food (ANS), the EU Commission has finally published the **Regulation (EU) 2022/860 amending Annex III to Regulation (EC) No 1925/2006 as regards monacolins from red yeast rice.**

The aim of the Regulation (EU) 2022/860

The aim of the Regulation (EU) 2022/860 is **limiting the use in foods and food supplements** by including the monacolins from RYR in **Part B** (substances subject to restrictions) and **Part C** (substances under Community control) of **Annex III of Reg. EC 1925/2006.**

References

⁽¹⁾EFSA NDA Panel scientific opinion on the substantiation of health claims related to Monacolin K (2013)

⁽²⁾Eu Pharmacopeia: (1S,3R,7S,8S,8aR)-8-[2-[(2R,4R)-4-Hydroxy-6-oxotetrahydro-2H-pyran-2-yl]ethyl]-3,7-dimethyl-1,2,3,7,8,8ahexahydronaphthalen-1-yl (2S)-2-methylbutanoate

⁽³⁾EU Commission draft proposal amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice

The summary

Here below, a summary which lists the main points at hand:

- Daily consumption shall provide **less than 3 mg of monacolins from RYR.**
- European Commission **refers to generic monacolins**, and not only to monacolin K.
- No transitional periods.
- The label shall include a list of warnings concerning its consumption.



ANALYTICAL SERVICE

In order to ensure that the product or ingredient meets the draft requirements, **Mérieux NutriSciences has developed a new analytical service to detect the monacolins:**

- 1 Standard analysis of monacolins K** - monacolin K hydroxyacid (MKA) and monacolin K in lactone form (MK) - on ingredients and finish product through the **HPLC-UV validated method**.
- 2 Advanced standard analysis of monacolins** on ingredients through the **HPLC-UV method**:
 - monacolin J hydroxyacid (MJA)
 - monacolin J (MJ)
 - monacolin M (MM)
 - monacolin L hydroxyacid (MLA)
 - monacolin X (MX)
 - monacolin L (ML)
 - compactin / mevastatin (P1)
 - dehydroxymonacolin (DMK)
- 3 On demand characterization of minor monacolins** on finished product.



REGULATORY SERVICES

Food supplements are required by Article 6 of Directive 2002/46/EC to be labeled with mandatory elements including the recommended quantity of product for daily consumption together with a warning not to exceed the stated recommended daily dose.

Mérieux NutriSciences **Expert Services Unit offers a range of services to assist companies in labeling of new or existing food supplements** to conform to continuously changing legal requirements.



**Mérieux NutriSciences can guarantee
that the product meets the requirements**



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