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## **Decision by the Food Safety Commission on** **Food Supplements containing Monascus purpureus (Red Yeast Rice)**

During the 295<sup>th</sup> meeting of the Food Safety Commission on the 6<sup>th</sup> February 2019, it was decided that:

In view of the European Food Safety Authority (EFSA) opinion -

(Link - <https://www.efsa.europa.eu/en/efsajournal/pub/5368> and <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5368>)

- Monacolin K in lactone form is identical to lovastatin
- Lack of data on RYR preparations (mixtures – variability in composition)
- RYR associated with ingestion of other botanicals (in the preparation or concomitantly) or of medicinal product
  - Possible side effects?
  - side effects observed after ingestion of monacolin K or lovastatin and not after ingestion of other botanicals
- Therapeutic dose of lovastatin 10-80 mg/day
  - Monacolin K effective dose for reducing cholesterol: 3 mg/day
- Adverse Effects (AEs) observed also at 3 mg monacolin K per day (2 weeks – 1 year)
  - rhabdomyolysis, hepatitis - Mazzanti et al., 2017
- Consistency in the AEs (++) musculoskeletal) reported after intake of monacolins and lovastatin

EFSA has not been able to set a safe level for the use of Monacolin K (AND in addition adverse effects have also been reported at low concentrations (3 mg per day)).

**Therefore:**

**Food Supplements containing Monascus purpureus (Red Yeast Rice). A daily intake of 10mg Monacolin K from Red Yeast Rice contributes to the maintenance of normal blood cholesterol levels.**

**The warning statements 'Per l'uso dei prodotto si consiglia di sentire il parere del medico. Non usare in gravidanza, durante l'allattamento e in caso di terapia con farmaci ipolipidemizzanti' of such products should be in English and/or Maltese.**

**These products can only be sold from Pharmacies.**

Hadrian Bonello

Secretary

Food Safety Commission