EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Regulatory Committee 2009/41/EC
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CIRCABC Link: *https://circabc.europa.eu/ui/group/47075858-2b2d-4be4-b426-80fb29f081ac/library/d6efe7b1-9ec4-4b1b-9a2b-1b53ba2dc452?p=1&n=10&sort=name_ASC*

SUMMARY REPORT

A.01 Inactivation of genetically modified micro-organisms - presentation by a Member State and discussion

Member States exchanged experiences as regards to several issues related to the inactivation of genetically modified micro-organisms (GMMs) and waste disposal practices following one Member State's presentation on assessment of GMMs microwave inactivation in accordance with the requirements of Article 4 (5) of Directive 2009/41/EC on the contained use of GMMs.

The Commission provided clarifications on the application of the requirements of Directive 2009/41/EC, particularly on the requirements for inactivation of GMMs, including on the possibility to use different methods, in accordance with the relevant provisions of the Directive.

A.02 Do-It-Yourself practice – presentation by a Member State and discussion

One Member State shared their approach to Do-It-Yourself (D-It-Y) practices and experience in applying biosafety requirements, e.g. identifying and raising awareness of the open science community on regulatory requirements of GMMs contained use.

Several other Member States informed the Committee of the approaches and procedures they have put in place to implement the Directive in D-It-Y situations.

The Commission will consider whether a follow-up discussion to allow for further exchanges is necessary.

A.03 Antibiotic resistance marker genes: phasing out under containment – presentation by a Member State and discussion

One Member State shared information on national guidelines in assessing antibiotic resistance marker genes within applications for contained use of GMMs, on conducting inspections and on activities undertaken by the manufacturing companies for phasing out of these genes.

Another Member State referred to the relevance of use of antibiotic resistance marker genes to the manufacturing of fermentation products.

Member States showed an interest on the national risk assessment guidelines mentioned above which will be shared with other competent authorities.

A.04 Regulatory status of certain products- presentation by a Member State and discussion

One Member State presented cases of micro-organisms for which the determination of their regulatory status as GMM under Directive 2009/41/EC may raise questions. The presentation focused on different cases for bacteriophages.

Other Member States shared their views on the presented cases and noted further microorganisms for which the application of the GMM definition in the Directive may need discussion (e. g. viral vectors, self-replicating RNA particles, cells that are modified and then re-modified to their original state). The interpretation of the GMM definition and the appropriate safety measures under contained use of GMM in these cases were discussed.

Some Member States pointed out that with the advancement of methods in biotechnology other issues in relation to the regulatory status of certain products would arise.

A.05 Any Other Business