

Annex I: Explanatory Notes

1. Introduction

Title of Regulations	Data Governance Regulations, 2024
Activity to be regulated	Voluntary data sharing for the benefit of businesses and citizens
Responsible entity	The Malta Digital Innovation Authority

2. Summary and Background

2.1 Aims and Objectives of the DGA

The Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (hereinafter referred to as the “DGA”) provides a framework to enhance trust in voluntary data sharing for the benefit of businesses and citizens.

The economic and societal potential of data is enormous: it can enable new products and services based on novel technologies, make production more efficient, and provide tools for combatting societal challenges. In the area of health, for example, data can contribute to providing better healthcare, improving personalised treatments and helping cure rare or chronic diseases. It is also a powerful engine for innovation and new jobs, and a critical resource for start-ups and SMEs. However, this potential is not being realised. Data sharing in the EU remains limited due to a number of obstacles (including low trust in data sharing, issues related to the reuse of public sector data and data collection for the common good, as well as technical obstacles).

In order to truly capitalise on this enormous potential, it should be easier to share data in a trusted and secure manner. The DGA is a cross-sectoral instrument that aims to regulate the reuse of publicly/held, protected data, by boosting data sharing through the regulation of novel data intermediaries and by encouraging the sharing of data for altruistic purposes. Both personal and non-personal data are in scope of the DGA, and wherever personal data is concerned, the General Data Protection Regulation (GDPR) applies. In addition to the GDPR, inbuilt safeguards will increase trust in data sharing and reuse, a prerequisite to making more data available on the market.

2.2 Aims and Objectives of the Data Governance Regulations, 2024

The Data Governance Regulations, 2024, aim to provide the necessary clarity to all involved stakeholders as to which governmental entities shall be responsible for the tasks imposed by the same regulations.

Given the nature of the proposal and that these regulations are an implementation of an EU regulation with no additional obligations imposed on local stakeholders by virtue of national requirements, stakeholders consulted were the Malta Information Technology Agency (MITA) and the Data Governance Council (DGC).

Following internal consultation, Malta Digital Innovation Authority (MDIA) was designated as the competent authority for data intermediation services and for the registration of data altruism organisations and the DGC was nominated as the competent authority to grant or refuse access for re-use data and the single point of contact. In addition to designating the mentioned competent authorities, the regulations further refer to the right to file a complaint, the right to an effective judicial remedy and infringements.

3. Overview of the structure of the instrument

The legislation proposed designates the national competent bodies for the purposes of the DGA. The new instrument consists of 10 regulations.

Regulation 1 gives the title of the regulations, their scope, that is, to implement the provisions of the DGA and the respective date for the coming into force;

Regulation 2 provides a list of definitions;

Regulation 3 designates the DGC as the national competent body for the purposes of Article 7 of the DGA;

Regulation 4 provides for the right of redress from any decision taken by a competent public sector body or by the DGC;

Regulation 5 designates the DGC as the single information point;

Regulation 6 designates the MDIA as the national competent authority for data intermediation services and data altruism organisations gives it all powers required as per the DGA for the fulfilment of its role. This regulation also gives the MDIA the powers required under Article 14 and 24 of the DGA which relate to the monitoring of compliance;

Regulation 7 provides for the right to file a complaint against a data intermediation services provider or against a recognised data altruism organisation;

Regulation 8 provides for the right to an effective judicial remedy and applies the provisions of Part IX of the Malta Digital Innovation Authority Act (Cap. 591a) to legally binding decisions made by the MDIA and to any failure of the MDIA to act on a complaint filed with it in accordance with regulation 6;

Regulation 9 deals with infringements against the DGA;

Regulation 10 provides for the necessary consequential amendments to the Second Schedule to the Administrative Justice Act (Cap. 490)

4. Commentary on parts and articles

Regulation number	Meaning and obligations placed on user
Regulation 3	<p>This regulation designates the DGC as the competent authority to assist the competent public sector bodies which grant or refuse access for the re-use of the categories of data referred to in Article 3(1) of the DGA.</p> <p>The DGC is empowered to grant access for the re-use of the categories of data referred to in Article 3(1) of the DGA</p>
Regulation 4	<p>This regulation gives the right of appeal before the Administrative Review Tribunal from any decision taken by a competent public sector body or the DGC in accordance with regulation 3, as well as the right of appeal from the decisions of the Tribunal to the Court of Appeal in accordance with the Administrative Justice Act (Cap. 490).</p>
Regulation 5	<p>This regulation states that the DGC shall be the body designated as the single information point. Persons may send enquiries or requests for the re-use of the categories of data referred to in Article 3(1) of the DGA.</p>
Regulation 6(1)	<p>This regulation designates the MDIA as the competent authority for data intermediation services and for the</p>

	registration of data altruism organisations.
Regulation 6(2)	The regulation empowers the MDIA to monitor compliance of data intermediation services providers and recognised data altruism organisations in accordance with the DGA.
Regulation 7	This regulation on the right to file a complaint holds that, persons may file a complaint in relation to any matter falling within the scope of the DGA, either individually or with the MDIA against a data intermediation services provider or against a recognised data altruism organisation.
Regulation 8	This regulation provides a right to an effective judicial remedy whereby Part IX of the MDIA Act applies to the legally binding decisions taken by the MDIA under Articles 14, 19 and 24 of the DGA and a failure of the MDIA to act on a complaint filed with it.
Regulation 9(1)	This regulation applies parts of the MDIA Act to certain infringements of the obligations regarding transfers of non-personal data to third countries, the notification obligation of data intermediation services providers, the conditions for providing data intermediation services and the conditions for the registration as a recognised data altruism organisation pursuant to the DGA
Regulation 9(2)	This regulation lists the criteria for the imposition of administrative penalties on data intermediation services providers and recognised data altruism organisations.
Regulation 9(3)	This regulation holds that prior to initiating proceedings in relation to infringements relating to transfers of non-personal data to third countries, the MDIA may, at its discretion, consult with the DGC or any other person.

5. Concluding Section

Should more information be required kindly contact the MDIA on 21828800 or at info@mdia.gov.mt.

N.B. This Explanatory Note is not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. This Note does not purport to be an authoritative ruling on the interpretation of the legislation.