Prior Checking Opinion

"The EU Platform for Rare Diseases Registration"
at Joint Research Centre-Ispra (European Commission)

Case 2015-0982

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All EU citizens and individuals residing in the EU with congenital anomalies or cerebral palsy may enroll in their local, regional or national registries, via dedicated databases and provide data related to their health. The Joint Research Centre (JRC) will use this information to perform statistical monitoring at European level and to produce scientific reports for DG SANTE and academic publications. JRC analysis/research aims at reducing mortality, anomalies, impairment and disabilities, improving quality of life, and promoting best practices for prevention and care for European citizens. Persons whose information is included in these databases are indirectly identifiable.

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Brussels, 17 June 2016

1. Proceedings

On 9 November 2015, the European Data Protection Supervisor ("the EDPS") received a notification for prior checking under Article 27(2)(a) of Regulation 45/2001 ("the Regulation") from the Data Protection Officer ("the DPO") of the European Commission. The

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notification concerns the development and maintenance of the European Platform on Rare Diseases Registration (the EU Platform) by the Institute for Health and Consumer Protection (the JRC).

This is not a new processing operation, but a continuation of the same activity carried out by two Central Databases, EUROCAT[1] and SCPE[2], located at the University of Ulster, UK and at the University of Grenoble, France respectively. In 2015, EUROCAT data were transferred and are now stored in the European Platform on Rare Diseases Registration being developed by JRC in collaboration with DG SANTE (the JRC Central Registry). The SCPE data as well as new data related to rare diseases will also be included in the JRC Central Registry.

As this is an ex-post case, the deadline of two months for the EDPS to issue his Opinion does not apply[3].

2. Facts

Rare Diseases were flagged as a political priority for the European Commission in 2008, in the Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions setting out an overall strategy to support Member States in diagnosing, treating and caring for EU citizens with rare diseases[4]. Since these diseases are rare, there is limited and very scattered information and expertise on them across Europe. This is why the EU action provides high added-value for Rare Diseases, pooling together knowledge and expertise and supporting the co-operation

[1] **EUROCAT (European network for the surveillance of Congenital Anomalies), is a network of 39 population-based registries in 21 countries** established in 1979 for the epidemiological surveillance of congenital anomalies. It covers one third of the European birth population (approx 1.7 million births/year). EUROCAT data enables provision of prevalence, prenatal diagnosis and perinatal mortality data highly relevant for European public health. Based on this data recommendations are developed for primary prevention in the Rare Diseases National Plans, for medicinal drugs, food/nutrition, lifestyle, health services, and environmental pollution. In the context of the Zika virus epidemic, EUROCAT data have been recently requested by an EU agency, the European Centre for Disease Control (ECDC). The existing EUROCAT data on microcephaly is invaluable and unique in this context and very much and urgently needed. There is great fear that the Zika infection may also be transmissible (via mosquitos) within the EU (especially the Mediterranean region) and as EUROCAT covers over one third of EU births, it can be an indispensable resources for monitoring, control and evaluation of microcephaly data since 1979 in Europe which will be the bottom line for future surveillance.

[2] **SCPE (Surveillance of Cerebral Palsy in Europe), is a network of 31 population-based registries for the surveillance of cerebral palsy (CP) in 23 countries.** Active since 1998, it disseminates knowledge for patients, health care professionals and key stakeholders, it develops best practice in monitoring trends in CP and it raises standards of equitable care for people with CP. Dissemination of this evidence-based information to policy makers is helpful to facilitate provision of appropriate, accessible, cost-effective care management programmes aimed to improve the quality of life for children and young people with CP and for their carers.

[3] On 11 February 2016, the EDPS contacted JRC for a videoconference for further information and clarifications. On 16 February 2016, a teleconference took place between the EDPS and JRC. On 17 February 2016 the EDPS asked the JRC to provide additional information and JRC and replied on 9 March 2016. Further clarifications were asked from the EDPS on 8 April 2016 and JRC replied on 18 April 2016. On 1st June 2016, the draft Opinion was sent to JRC for comments and JRC replied on 9 June 2016.

[4] COM(2008) 679 final

between Member States. Currently, patients with Rare Diseases often spend years of uncertainty waiting for their disease to be diagnosed, and for an appropriate treatment to be found. These difficulties affect approximately 30 million people in the European Union due to the enormous number of Rare Diseases (between 6000 and 8000).

Purpose

The purpose of the JRC Central Registry is to enable data analysis within and across many Rare Diseases and to facilitate clinical trials, support recommendations, policies, guidance and decision-making in public health. The data analysis aims at contributing to the research on reducing mortality, anomalies, impairment and disabilities, improving quality of life, and to promoting best practices for prevention and care for European citizens. To this end, the JRC Central Registry will include historic data from EUROCAT and SCPE; future data from these two databases will be fed into the Central Registry as well. Until now, both EUROCAT and SCPE data have been used to provide public health indicators, guidelines for best practices on health information, periodic monitoring and evaluation.

Persons affected

All EU citizens and individuals residing in the EU with congenital anomalies or cerebral palsy may enroll in their local, regional or national registries[5]; parts of the information in the local, regional or national registers are then fed into JRC-EUROCAT and JRC-SCPE Central Registries. Participants can only be fully identified at their local, regional or national registry. Identification is needed for managing different data sources, checking for duplicates, validation and data quality at local, regional or national level and not at the JRC Central Registries where anonymous codes are used.

Legal basis and lawfulness

- Title XIV, Article 168 of the Treaty on the functioning of the EU on public health[6];

[5] National registries can be any local healthcare provider (i.e. hospital, research University on genetics and epidemiology etc.) which can potentially be involved in the registration of the participants.

[6] *1."A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards* ***improving public health****, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as* ***health information*** *and education, and monitoring, early warning of and combating serious cross-border threats to health. 2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the* ***establishment of guidelines and indicators****, the organisation of exchange of best practice, and the* ***preparation of the necessary elements for periodic monitoring and evaluation****".*

- Communication of 11 November 2008 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe's Challenges. [COM(2008) 679 final][7];

- Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02)[8];

- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[9].

Procedure and data processed

In December 2013, JRC signed an Administrative Arrangement (AA) with DG SANTE. The latter entrusts JRC with the transfer of the EUROCAT and SCPE central databases to the JRC and the JRC to maintain and operate them as the JRC Central Registry. This objective of the AA was conceived in order to offer a sustainable solution for the continuation of the EUROCAT and SCPE activities, whose central activities have been funded from their establishment by the European Commission in the frame of successive projects and health programmes. This solution aims to keep the EUROCAT and SCPE systems functioning and to secure the results of valuable scientific work done over decades, highly relevant for European public health. Among other objectives, JRC must continue the data processing as it has been done before at the EUROCAT and SCPE Central Databases in Ulster, UK and Grenoble, France, give feed-back to the registries about their data and provide European-level analysis and results for the scientific community, healthcare providers, patients and policy makers.

In September 2015, JRC signed a Collaboration Agreement with the individual registries of the EUROCAT network. In January 2016, JRC signed a Collaboration Agreement with the individual registries of the SCPE network. The roles and responsibilities of JRC and of the registries (local, regional or national) are detailed in the two agreements. They provide the framework for the registries to transmit data to the JRC Central Registry and for the JRC to operate the two Central Databases, but also the obligation of the JRC to provide feed-back to the registries, to analyse the data and to provide the results of the data processing to the

[7] Article 5 on Operational Actions to Develop European Cooperation and Improve Access to High-Quality Healthcare for Rare Diseases; Article 5.11 on Registries and databases: *"**Registries and databases constitute key instruments** to increase knowledge on rare diseases and develop clinical research. They are the only way to pool data in order to achieve a sufficient sample size for epidemiological research and/or clinical research. **Collaborative efforts to establish data collection and maintain** them will be considered, provided that these resources are open and accessible. A key issue will also be to **ensure the long-term sustainability** of such systems, rather than having them funded on the basis of inherently precarious project funding. This idea was also elaborated in the document "Improving access to orphan medicines for all affected EU citizens", adopted by the High level Pharmaceutical Forum".*

[8] Article II.5 on *Adequate Definition, Codification and Inventorying of Rare Diseases : "Consider **supporting** at all appropriate levels, including the Community level, on the one hand, specific disease information networks and, on the other hand, **for epidemiological purposes, registries and databases,** whilst being aware of an independent governance".*

[9] Article 12(2)(e) "*to reinforce research, **epidemiological surveillance like registries** and provide training for health professionals*"; Article 13(a) "*make health professionals aware of the **tools available to them at Union level to assist them in the correct diagnosis of rare diseases**, in particular the Orphanet database, and the **European reference networks**".*

registries/networks and to all stakeholders and general public. A Management Committee is established for each network. The committees meet at least three times a year to coordinate the execution of the activities of the JRC-EUROCAT[10] and JRC-SCPE[11] networks and take decisions under the above agreements.

Participants provide various categories of information to their local, regional or national registry. This information includes birth date, gender, multiple birth, birth weight, gestational age, death age, date of birth of the mother, place of birth (i.e. hospital), area of residence (i.e. municipality), mother's residence code, medical prescriptions, medical diagnosis and tests results, medical classifications used in every hospital[12] and socio-demographic data (maternal education[13], socioeconomic status of the mother and of the father, migrant status). Health problems are very often related to those variables that are proxies of lifestyles and potential dangerous expositions. They are collected because they could be important to identify subgroups in the population that have different needs for research and public health purposes.

On the basis of this information, JRC staff i. will perform statistical monitoring at European level to evaluate prevalence of congenital anomalies, clusters and trends, to detect new or increasing teratogenic exposures which may require public health action; ii. will develop recommendations considered for primary prevention in the Rare Diseases National Plans for medicinal drugs, food/nutrition, lifestyle, health services, environmental pollution; iii. will produce scientific reports for DG SANTE and for academic publications. The results of the data analysis in the reports will be aggregated.

Individual registries (local, regional or national) transmit the data from their covered population annually to the JRC Central Registry. The data transmitted do not include names. An alphanumerical code corresponding to each case is shared by registries.

Recipients

The notification states: "The recipients of the data are the staff working under the authority of the controller at JRC and the processors working on behalf of the controller. The recipients of the results of the data analysis (aggregated) are:
- DG SANTE (scientific reports) and
- Academic and lay publications, publicly available websites (public reports)".

Right of information

According to the notification, JRC refers to Article 12(2) of the Regulation and states that providing information would require a disproportionate effort to reach all the cases contained in the databases (many deceased).

[10] 7 representatives of the EUROCAT Network and 2 representatives from JRC.
[11] 6 representatives of the SCPE Network and 2 representatives from JRC.
[12] For example, International Statistical Classification of Diseases and Related Health Problems 9th and 10th Revision – WHO international standard in order to code the medical conditions of the cases; Paris nomenclature for Karyotypes; Bimanual Fine Motor Function Classification (BFMF); Gross Motor Function Classification (GMFCS); Manual Ability Classification System (MACS);Viking Speech Scale (VSS).
[13] In light of the International Standard Classification of Education of 1997 assigned according to the highest level of education completed.

Every individual EUROCAT/SCPE registry is responsible for obtaining the necessary approval and establishing ethics, data protection and consent arrangements to operate their local, regional or national EUROCAT/SCPE database and to comply with institutional and national requirements.

Some registries provide an information notice and an opt-in consent form to the participants[14]; others provide an information notice and an opt-out option[15].

Rights of access and rectification

The notification states that the right of access and rectification are not applicable due to Article 20(2) of the Regulation.

Retention policy

According to the notification, keeping past data together with data received annually is a requirement for identifying changes in occurrence of events of interest over time and place and for statistical monitoring of clusters and trends over time.

Following further clarifications provided by the JRC, all data stored in the JRC Central Registry are kept indefinitely.

Furthermore, the publications, scientific projects, or public health requests, approved by the Management Committees of each network respectively, are archived for 10 years for documentation purposes. This retention period is generally adopted for scientific journals from the scientific community.

Security measures

JRC provided the following documents:
- "Scope of security for JRC-EUROCAT information system";
- "Security plan for JRC-EUROCAT" and
- "Implementation plan for JRC- EUROCAT information system".

These documents provide "the definition of the security related scope and boundaries for the system", "the Security Plan Definition document for the JRC-EUROCAT system according to the EC specific security framework" and "the description or references for the processes used by this system" respectively.

[14] The registration system requires a legal authorisation or an ethical approval from local/national ethical committees or data protection authorities. An explicit written consent is required for registration.

[15] The registration system requires a legal mandate or an ethical approval for establishing the registration system. Participants are informed through an information notice and they can communicate their willingness not to be part of the registration.

3. Legal aspects

3.1. Prior checking

The processing of personal data under analysis is carried out by an EU institution, JRC of the Commission. Furthermore, the processing is both manual - which forms part or is intended to form part of a filing system (assessment, coding, classification, and reports with the results of data analysis) - and automatic (information provided by the participants through the local, regional or national registries EUROCAT/SCPE and then transmitted to the JRC Central Registry). The Regulation is therefore applicable.

Although the names and surnames of the participants are not transferred to the JRC Central Registry, the participants can be indirectly identifiable by the information (as described in the facts), which is transferred and stored in the JRC Central Registry[16]. For instance, a participant can be indirectly identified by some elements of his/her medical diagnosis, by the information of the socioeconomic status of his/her mother and the name of the hospital. It follows that all the information transferred and stored in the Central Registry are personal data related to the participants within the meaning of Article 2(a) of the Regulation.

The processing operation involves the processing of data relating to health, namely medical prescriptions, medical diagnosis, tests results and medical classifications.The purpose of the processing is to enable European-wide data analysis, to facilitate epidemiological, clinical trials and research, support recommendations, policies, guidance and decision-making in public health for the European citizens' better life quality, care and prevention. Due to the sensitive nature of the data processed, the processing is likely to present specific risks to the rights and freedoms of the applicants and it is therefore subject to prior checking by the EDPS[17].

3.2 Concept of controller

JRC has signed Collaboration Agreements with individual registries of the EUROCAT and SCPE networks.

The purpose of the processing under analysis is the transfer of the data from the two networks to the JRC Central Registry, their storage and their analysis by the JRC experts in order to produce scientific reports for prevention and care of the European citizens. It is JRC and not the EUROCAT and SCPE networks which are responsible for determining the purpose and the means of the processing, once the data are transferred to the JRC Central Registry. JRC is therefore the controller of the data which are transferred, stored and analysed in the JRC Central Registry (Article 2(d) of the Regulation).

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16 *'personal data' shall mean any information relating to an identified or identifiable natural person hereinafter referred to as 'data subject'; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity*" (Article 2(a) of the Regulation.

17 Article 27(2) of the Regulation contains a list of processing operations that are likely to present risks to the rights and freedoms of data subjects by virtue of their nature, their scope or their purposes, including point (a) processing of data relating to health.

The EDPS will identify below the practices which do not seem to be in conformity with the principles of the Regulation and provide JRC with relevant recommendations

3.3 Lawfulness, sensitive data, legal basis

The lawfulness of a processing must be justified on the basis of one of the five legal grounds under Article 5 of the Regulation.

As the notification correctly states, the processing under analysis is considered to be lawful under Article 5(a) of the Regulation.

Article 5 (a) of the Regulation requires two elements: the processing must be based on the Treaties or on an EU legal instrument and it must be necessary for the performance of JRC carried out in the public interest based on the Treaties. The EDPS considers that the above legal norms, outlined in the facts, may justify the processing in general, but they are not sufficient legal basis for the processing of data related to health, as it is the case under analysis.

The EDPS draws the attention to JRC that the processing under analysis concerns data related to health, which are considered to be sensitive under the Regulation and their processing requires a specific legal basis. Article 10(1) of the Regulation prohibits the processing of personal data concerning health, unless grounds can be found under Article 10(2), (3) or (4) of the Regulation.

The prohibition of the processing of data concerning health in the case under analysis could have been lifted, had the participants given their express consent to the processing of their medical data, in light of Article 10(2)(a) of the Regulation. As JRC pointed out, for getting the "express consent", the EUROCAT registries would need to contact over 380,000 patients (many deceased) and this would have marked the end of this activity for the EU. This possibility is therefore not an option and Article 10(2) cannot be an appropriate legal ground for lifting the prohibition of the processing of data related to health.

Article 10(4) of the Regulation provides that the prohibition of the processing can be lifted, if, "subject to the provision of appropriate safeguards, and for reasons of substantial public reasons of substantial public interest" ... an exemption "may be laid down in the Treaties or other legal instruments". Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare cannot justify the processing of data related to health under analysis, since it is a general one. However, Article 12(5) of the Directive empowers the Commission to adopt a delegated act which would set out the criteria and the conditions that the EUROCAT and SCPE networks should fulfil and respect[18]. A delegated act could therefore be considered to be an appropriate specific legal basis for the processing under analysis. Such legal instrument would thus set out the process of the processing with legal certainty, safeguards and clarity in the interest of both JRC and of the participants.

[18] See also recital 60 of Directive 2011/24/EU: "The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of measures that would exclude specific categories of medicinal products or medical devices from the recognition of prescriptions, as provided for in this Directive. **In order to identify the reference networks which should benefit from support by the Commission, the Commission should also be empowered to adopt delegated acts in respect of the criteria and conditions that European reference networks have to fulfil**."

Recommendation:
Due to the processing of data related to health, a delegated act should be adopted, so that the processing of such sensitive information, which is in principle prohibited, can be lawfully justified.

JRC should inform the EDPS about the feasibility of the adoption of a delegated act and/or of any other alternative means which can establish the lawfulness of the processing of data related to health under analysis.

3.4 Rights of access and rectification

JRC intends to use the exemption under Article 20(2) of the Regulation in order not to grant the rights of access and rectification to the participants.

Under Article 20(2) of the Regulation, when data are processed solely for scientific research, the right of access and rectification cannot be applied, provided that there is clearly no risk of breaching the privacy of the data subjects and that the controller provides adequate legal safeguards, in particular to ensure that the data are not used for taking measures or decisions regarding particular individuals. JRC indeed processes data for purely scientific purposes and given the fact that the participants are not directly identifiable by the JRC, there seems to be no risk of breaching their privacy. As to whether JRC provides adequate legal safeguards, the data are processed for scientific research purposes, they are not used for taking individual decisions on the participants and they are not transferred to other entities. In addition, the rights of access and rectification can be exercised at a national level, JRC should provide a general privacy notice to the participants via the national registries (see point 3.6 on information to be provided to the participants) and JRC has taken appropriate security measures at least for EUROCAT (see further point 3.7 on security).

Articles 13 and 14 are therefore not applicable in this case, provided that JRC adopts adequate legal safeguards, as it is required under Article 20(2) of the Regulation.

It is understood that national registries will keep the information provided to JRC up to date, so that any changes in records at the national level (e.g. updates, rectification or any other changes) will be reflected in the data held by JRC.

3.5 Data retention

As a general principle, Article 4 (1) (e) of the Regulation states that personal data must not be kept in a form which permits identification of individuals for longer than is necessary for the purposes for which the data were collected or for which they are further processed.

Following further clarifications provided by JRC, all data stored in the JRC Central Registry are kept indefinitely.

The EDPS acknowledges that JRC needs past data to compare them with the more recent ones for the annual scientific analysis and reports. However, JRC, under Article 4(1)(c) of the Regulation, is obliged to set out a maximum retention period for the data processed, which is necessary to the purpose for which they were collected or further processed. JRC should therefore make an assessment, in light of Article 4(1)(e) of the Regulation, as to keeping the data indefinitely is necessary for present and future scientific research, analysis and reports and establish a maximum retention period.

Recommendation:
JRC should make an assessment as to whether historic data are still necessary for its present and future scientific research, analysis and reports and establish a maximum retention period.

3.6 Information to be provided to the participants

According to the notification, JRC refers to Article 12(2) of the Regulation and states that providing information would require a disproportionate effort to inform the participants. Since JRC processed data for scientific research and the participants are not directly identifiable by the JRC, Article 12(2) is indeed applicable in this case. However, the provision explicitly requires that if it involves a disproportionate effort, JRC should provide for "appropriate safeguards after consulting the EDPS".

An appropriate safeguard would be for JRC to prepare a general privacy notice and communicate it to the national registries.

As to the content of the privacy notice, JRC should in particular,

i) refer to the legal basis justifying the processing of data related to health and establishing the JRC Central Registry;
ii) clarify the role of JRC and the purpose of the processing of the data of the participants by JRC;
iii) indicate all recipients of the data processed;
v) mention that the participants may exercise their right of access to and rectification directly to their national registries and explain the reason. JRC should be informed from the national registries accordingly (point 3.4);
vi) indicate the retention period of the data kept in the JRC Central Registry, after carrying out the assessment as recommended by the EDPS in point 3.5) and
vii) refer to their right to have recourse at any time to the EDPS.

Recommendation:
JRC should communicate the privacy notice to the national registries and ensure that they include a link to the JRC privacy notice in the information which is provided to the participants enrolling in the national registries.

3.7 Security

Article 22 of the Regulation obliges the controller to implement appropriate technical and organisational measures to ensure a level of security appropriate to the risks represented by the processing.

JRC has documented the information security risk analysis performed and the security measures chosen to address the risks identified for EUROCAT. However, the documents provided seem to be draft documents and they do not seem to have been approved by the controller, JRC. JRC should therefore approve both the information security risk assessment performed and the residual risks remaining after the security measures are implemented.

As to the "Implementation plan" for the security measures mentioned above, there is no indication as to whether the said security measures have already been implemented or are intended to be implemented and if it is the case, when they will be implemented. Furthermore, there is no evidence as to whether JRC has formally approved the implementation plan or not.

Recommendation:
JRC should

1. approve the information security risk assessment performed,
2. update the implementation plan with the information about the status of the different security measures and appropriate planning when needed, and
3. approve the updated version of the implementation plan.

Furthermore, JRC has not provided any security documents for SCPE Information System.

Recommendation:
JRC should carry out a security risk assessment for SCPE, similar to the one for EUROCAT and take into account the recommendations mentioned above.

4. Conclusion

There is no reason to believe that there is a breach of the provisions of the Regulation provided that the following considerations are taken into account. In particular JRC should:

- inform the EDPS about the feasibility of the adoption of a delegated act and/or of any other alternative means which can establish the lawfulness of the processing of data related to health under analysis. (point 3.3);

- make an assessment as to whether historic data are still necessary for its present and future scientific research, analysis and reports. A maximum retention period should be set out (point 3.5);

- prepare a privacy notice, include all information pointed out in point 3.6 and ensure that the national registries include a link to the JRC privacy notice in the information which is provided to the participants enrolling in the national registries;

- approve the information security risk assessment performed for EUROCAT, update the implementation plan with the information about the status of the different security measures and appropriate planning when needed, and approve the updated version of the implementation plan (point 3.7);

- carry out a security risk assessment for SCPE, similar to the one for EUROCAT and take into account the recommendations mentioned above (point 3.7).

In the context of the follow-up procedure, please send to the EDPS a revised version of the notification, privacy notice, and the security documents for EUROCAT and SCPE within a period of three months, to demonstrate that the above EDPS recommendations have been implemented.

Done at Brussels, 17 June 2016

Wojciech Rafał WIEWIÓROWSKI