1. Introduction

The regulation (EC) No. 1907/2006 (REACH), which came into force 01/06/2007, caused extensive reorganisation in the area of chemical legislation. The REACH regulation applies directly in every member state of the European Community as well as Iceland, Liechtenstein and Norway and requires no conversion into national law. The REACH regulation does not apply in Andorra, San Marino or Switzerland.

EU REACH shifts the responsibility for collection, evaluation and assessment of material data from the authorities to the industry (burden of proof). The basic principle is: “No data, no market”. As a result, all members of the supply chain must contribute to the protection of human health and the environment with regard to all substances they produce, distribute or use. In view of REACH and the increased responsibility of individual companies, it is important for those with hazardous substances in their portfolio to carefully consider which ones should be retained in the long term and which ones can be phased out. The process of finding viable solutions to the implementation of REACH for sintered parts manufacturers, which is also acceptable to the market, requires communication with competent partners along the supply chain.

REACH replaces a large number of existing regulations and directives and radically impacts fundamental chemical legislation. Not every company is equally affected by REACH. Depending on which role(s) an enterprise has in the value adding chain (manufacturer, importer, only representative, downstream user, and formulator) and which kind of products are produced, distributed or imported, different obligations arise. The REACH requirements affect the processes of a company in many areas simultaneously: QM, IT, HSE, product portfolio, material portfolio, liability, documentation, communication). This article looks at REACH exclusively from the view of the manufacturer of sintered parts and thus covers only one small part of the REACH requirements. The following explanations are based on the experience and the understanding of the authors and are not necessarily comprehensive and correct.

2. The role of the manufacturer of sintered parts under REACH

Under REACH the sintered parts manufacturer has the role of the Downstream User (DU). According to article 3 (13) [1] a DU is “Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or
professional activities. A distributor or a consumer is not a downstream user.” If a manufacturer of sintered parts is mixing powders, then he acts in the role of a DU, which elaborates mixtures (of preregistered/registered substances). Because the manufacturer of sinter parts does not normally distribute these in-house mixtures but uses them only on the company premises to produces PM parts, no additional obligations result from his role as formulator. If these in-house powder mixes contain materials classified as dangerous, and if these mixes are transported on public roads, then the supply of a safety data sheet (SDS) as well as appropriate labelling of the container is required.

The manufacturer of sintered parts should make certain when ordering powder, additives and process media, that these originate from companies within the European Union and/or that the invoice is issued within the European Union. If this is not possible, then the manufacturer of sintered parts can also fall into the role of Importer with all the associated REACH obligations, in particular the requirement of registration. In this case, in principle, the import should take place by a sales office within the EU or by the manufacturer’s appointed Only Representative who is based in the European Union. Appropriate regulations regarding the appointment of an Only Representative can be found in article 8 (3) [1] of the REACH regulation.

The manufacturer of sintered parts is a producer of articles. An article according to section 3 (3) [1] means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Packaging as such is according to section 3 (3) [1] also an article [2].

3. REACH obligations as manufacturers of sintered parts

The obligations of a DU depend on the exact activities it carries out with a substance or a mixture. The role as a DU manufacturer of sintered parts has the following obligations, as listed under 3.1 to 3.5. Obligations, which apply to the area of Product and Process Oriented Research and Development (PPORD), are not considered in the following list.

3.1 Duties to supply information regarding the “Substances Of Very High Concern“ (SVHC) in articles

The SVHC-list usually is completed twice a year, in June and December. Substances, which are listed, have the following characteristics:

- Carcinogen category 1A or 1B, in accordance with appendix I, section 3,6 of the regulation (EEC) No. 1272/2008 [3]
- Mutagen category 1A or 1B, in accordance with appendix I, section 3,5 of the regulation (EEC) No. 1272/2008
- Toxic to reproduction category 1A or 1B, in accordance with appendix I, section 3,7 of the regulation (EEC) No. 1272/2008
- Persistent, bio-accumulative, toxic (PBT materials), in accordance with appendix XIII of the REACH regulation [1]
• Very persistent, very bio-accumulative (vPvB), in accordance with appendix XIII of the REACH regulation
• Substances with Equivalent level of Concern (ELOC), are substances which may have serious effects on human health and/or on the environment according to scientific findings and whose effects are just as worrying, as those of the materials listed before. Materials of this category are to be determined in accordance with the procedure of article 59 of the REACH regulation [1]. Examples of such materials are substances with endocrine effect, e.g. substances, which can act like (environmental) hormones and disturb the equilibrium of the hormone system of humans and animals

If the concentration of an SVHC candidate in the article is >0.1 weight by weight-%, the customer must be informed immediately, regardless of whether such information has been requested or not (article 33) [1]. The minimum requirement is to communicate the name of the substance as well as information for the safe use of the product. A special format is not prescribed. This duty to supply information is independent of the production volume. To final consumers this information must be provided on request within 45 days after the inclusion date of the substance into the SVHC list.

Is the concentration of the SVHC is >0.1 weight by weight-% and the consumption per year more than 1t, then the European Chemical Agency (ECHA) in Helsinki needs to be notified at the latest 6 months after the entry-date into the SVHC-list (article 28 (5)) [1]. The notification is made via IUCLID5 and REACH IT. This notification obligation is not required, if the substance is already registered for that specific use (article 7 (6)) [1] or if the manufacturer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal (article 7 (3)) [1].

Additionally, the registry of nominated substances for inclusion on the SVHC list must be monitored, so that in case of inclusion of a substance, all necessary information is available in a timely manner to fulfil the substitution requirement and/or to submit notification within the prescribed period. The SVHC list and the materials nominated for the SVHC list can be seen on the REACH web site (ROI).

With respect to the SVHC list, dated the 19th of December 2012, manufacturers of sintered parts could be concerned by boric acid, borates and CrVI compounds. Boric acid and borates are ingredients of soldering powders in concentrations of >0.1%. In some cooling fluids the concentration of boric acid is up to <5.5%. Galvanised zinc layers can be black or yellow-chromated for the reason of passivation. Here it should be checked whether the passivation layer is free from CrVI compounds. A conversion to CrVI free alternatives such as e.g. blue or thick-film passivation should have already been completed, as different material legislation, e.g. directive No 2000/53/EC on the End of Life Vehicle as well as the directives RoHS No. 2002/95/EG and RoHS No 2011/65/EU for the Restriction of the use of certain Hazardous Substances in electrical and electronic devices did limit the use of CrVI-compounds before the REACH regulation came into force.
In the future manufacturers of PM parts might be affected if cobalt enters into the SVHC list. On the ECHA website substances which may be considered as SVHC candidates are listed in the ROI (Registry Of Intentions for SVHC proposals).

3.2 Conformity with respect to Annex XIV; the uses of these substances require authorisation

Substances on the SVHC list may be subject to authorisation. At least every other year, the ECHA recommends SVHC candidates for inclusion in Annex XIV. Priority will be given to substances with PBT- and vPvB-properties and those with wide dispersive use or large amounts of marketing.

The substances listed in Annex XIV may not be placed on the market and may not be used as substance or in mixtures or in articles. Authorisation can be granted for particular uses within the relevant supply chain (Article 56). [1]

The provisions concerning the substances subject to authorization shall apply without volume threshold for even the smallest amounts. The inclusion of a substance in Annex XIV means that, practically speaking, this substance is to be banned from the EU. Authorisations are granted by the European Commission for a limited time, if according to Article 60 (2) [1] the risk to human health or environment arising from the use of the substance is adequately controlled (“Adequate control route”). Another route to authorisation, according to Article 60 (4) [1], is to demonstrate that the socio-economic benefits outweigh the risks arising from the use of the substance on human health or the environment, and that there are no suitable alternative substances or technologies that are economically and technically viable (“Socio-economic benefit route”) [1].

Until at least 18 months before the so-called sunset date an authorisation can be submitted. After the sunset date, the use and placing on the market of a substance is permitted only if an authorisation is granted. Where a DU considers his use as confidential or the supplier has no interest in considering this particular use in his application, the DU can as a last option apply for authorisation himself. However the time required and the costs are substantial. It is estimated that the application for authorisation, including the Chemical Safety Report (CSR), Socio-Economic Analysis (SEA), analysis on alternatives and substitution plan takes about 24 months. It should be noted that for the application for authorisation a CSR is always required regardless of the volumes considered [4].

The fee for application for authorisation can be found in the Fees Regulation (EC) No 340/2800. For a mid-sized company the fee for authorisation is 40.000 Euro plus the fee for the substance and use, each 8000 Euro [5].

When the authorisation is granted there still remains the requirement of minimisation, which means that the holder of the authorisation must ensure that the exposure is reduced to the lowest level that is technically and practically feasible (Article 60 (2)
Besides the requirement of minimisation it is also necessary to examine possible substitutes to assess their impact.

The uses for which authorisation has been granted are set out in Section 15.1 of the SDS. The DU that uses the authorised substance shall notify the Agency within three months of the first supply of the substance (Article 66). [1]

In order to take appropriate measures in good time, it is advised to follow the list of the nominated substances for Annex XIV on the ECHA website.

According to our knowledge, currently for manufacturers of sintered parts there are no causes for concern that arise with regard to Annex XIV (status Jan. 2013).

3.3 Conformity as regards Annex XVII
Substances with restriction on uses, up to banned substances

Annex XVII of the REACH regulation adopts Annex I of the former Directive 76/769/EC. Annex XVII lists substances and compounds with restrictions on usage, placing on the market, on uses and additionally with restrictions on manufacturing. Thus the scope of Annex XVII is wider than that of Annex XIV where the registration procedure does not capture the manufacturing of substances. In that case, for substances that require authorisation, manufacturing is still permitted e.g. for export purposes [6]. By contrast, restrictions are applicable immediately, therefore from this perspective, the authorisation process is the less restrictive method.

Restrictions may apply to certain individual uses of substances; however they can also capture all uses of a substance (a banned substance). If all uses are restricted then this substance can no longer be included in Annex XIV. The condition for introducing new restrictions on substances, either on their own, in mixtures or in articles, is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on market, which needs to be addressed on a Community-wide basis (Article 68 (1)) [1].

All uses of a substance, other than the restricted ones, are permitted. However substances listed in Annex XVII can be subject to authorisation. Whilst the authorisation process is in process the defined restrictions must be considered.

Restrictions also apply to the Product and Process Oriented Research and Development (PPORD) but not for Scientific Research and Development (SR&D).

A variety of substances with restrictions are used by manufacturers of sintered parts on their own, in mixtures or in articles. If a substance by itself or in a mixture is part of Annex XVII it must be noted in section 15.1 of the SDS. For substances with restrictions it is necessary to determine whether your own use is prohibited. The compliance of the business to each restriction needs to be examined and documented.

For example, the restrictions for Nickel are defined in item 27 of Annex XVII. Nickel may not be used in articles intended to come into direct and prolonged contact with the skin if the rate of Nickel release from the parts of these articles is greater than 0.5µg/cm²/week. The purpose of this restriction is to protect consumers against nickel
allergies, which may be caused by prolonged contact with nickel-releasing products such as in jewellery, buttons, zippers and rivets in garments. [7]

In the directory “Registry of current restriction proposal intentions” on the ECHA website further information concerning future restrictions on uses or banned substances can be found.

3.4 Registration requirement (Article 6) [1]

Registration requirements exist for substances which are produced and placed on market in quantities >1t/a. The registration obligations lie with the producers and importers of chemical substances. DU should as far as possible provide information to assist the preparation of registration dossiers. DU have the right to inform their suppliers about their own uses of the substance so that that use becomes an “identified use” in the registration dossier and will be considered in the ES and enter in the SDS in Section 1 as “identified use”.

As a rule, DU have no registration obligations. However according to Article 7 (1) [1] the producer or importer of articles shall submit a registration to the Agency for any substance on its own or in a mixture contained in those articles, if the substance is present in said articles in quantities totalling over one tonne per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use. This registration obligation of the DU shall not apply to substances that have (even outside of the supply chain) already been registered for that use (Article 7(6)) [1]. Uses that are registered are listed on the ECHA website under “Registered substances”. Here registered uses are described with the help of the descriptor system. In the SDS the description of identified uses can be phrased freely but ideally the descriptor system should also be used for this purpose.

The information on substances in articles as well as the information about safe use of the product should be provided as product safety information or similar but not as an SDS. According to Article 31 [1] SDS are not allowed for articles [8].

Manufacturers of sintered parts that produce oil-impregnated bearings are only affected by the obligation of registration if the supplier of the oil has not already considered the present use. However, it is in the interest of oil producers, to keep the list of identified uses as wide as possible so that all established uses are covered. Registration numbers are communicated in Section 3 of the SDS, provided that the relevant substances have already been registered.

3.5 Duties linked to safety data sheets (SDS)

The SDS is the central instrument of information transmission and under REACH acquires greater importance than it previously had [9]. Each DU needs to keep available all the information he requires to carry out his duties under REACH for a period of at least 10 years after the last use of a substance/mixture (Article 36) [1]. As a consequence, SDS need to be kept at least for 10 years. According to Article 35 [1] SDS must be accessible by employees who work with hazardous substances/mixtures at any time. All participants in the supply chain are asked to contribute so that all intended uses for a substance/mixture are considered in the registration dossier and
will therefore be included in the SDS as identified uses. Essential to ensuring the suitability of SDS for operations is close communication between producers and users, in order to include all relevant information in the CSR and SDS. Of importance here is communication regarding specific uses, exposures and appropriate Risk Management Measures (RMM). In the future SDS should provide all information required by the DU in order to assess exposures occurring with regard to use of the substance, and information about appropriate RMM in order to guarantee and demonstrate safe use. The SDS should guide the users through carrying out the correct on-site risk assessments [10].

SDS can be requested by the DU in accordance with Article 31 (3) [1], even if a solid or liquid mixture is not classified under the following circumstances:

- An ingredient meets the criteria for classification as hazardous
- An ingredient is persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB)
- The mixture contains a substance in a concentration of \( \geq 1 \) wt.-% for which there are Community workplace exposure limits

It is not guaranteed that in Section 15.1 of the SDS or in the safety information (SI) all the existing restrictions on uses in Germany are listed. Note also that the supplier is obliged to supply updated SDS or SI for 12 months after the last delivery [11].

Where reference is made in an extended Safety Data Sheet (e-SDS) to waiving, this means that the supplier waived well-founded testing procedure and has the consequence for the user that the described conditions of use must be strictly adhered to. If the substance goes into an article, it must be ensured that the substance is not released during its life cycle and the exposure is negligible.

At the latest, from 12/1/2012 SDS must meet the requirements of Annex II of the REACH Regulation, which was amended by Regulation (EU) No 453/2012) in terms of form and content of a SDS as well as the implementation of the CLP classification for substances and mixtures in SDS.

### 3.5.1 Plausibility check on safety data sheets

According to the Occupational Safety Act and the Regulation on Hazardous Materials it is required that under duty of care, SDS must be checked for errors and deficiencies. The recipient of a SDS needs to ensure to the extent possible, that the SDS is technically correct and complete. The DU is responsible for informing the supplier if he questions the adequacy or appropriateness of risk management measures presented in the SDS for identified uses (Article 34b) [1].

### 3.5.2 Check on conformity on uses by means of the SDS and Exposure Scenarios (ES)

For substances where a Chemical Safety Report (CSR) was created an e-SDS must be provided. A CSR will be created for substances that meet the criteria for classification as dangerous or PBT or vPvB and are produced or imported in quantities of \( \geq 10 \) t/a.
An e-SDS is a SDS with attached ES. An ES means the set of conditions, including operational conditions and RMM that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends that the DU controls the exposure of humans and the environment. These ES may cover one specific process or use or several processes or uses as appropriate (Article 3 (37) [1]. Depending on classification and volume of a substance the period to provide ES can extend to the third registration period in 2018, when only registered substances can ES be submitted.

For mixtures, ES will not be available because they are not required to be developed [12]. The creator of SDS for mixtures may attach the ES of the lead substance for classification of a mixture to the SDS. Alternatively, when compiling the SDS, relevant information from the ES can be implemented in the appropriate sections of the SDS of the mixture (Article 37 (2) [1]. Which option will become established on the market or advocated by controlling authorities remains to be seen.

When the DU receives an e-SDS, he must consider whether the existing ES covers its uses. If their own use is not covered, the DU shall have the right to make its use (as a minimum a brief general description) known in writing to the manufacturer, importer, DU or distributor who supplies the substance either on its own or in a mixture, with the aim of making this an identified use. In making a use known, the DU shall provide sufficient information to allow the supplier to prepare an ES, or if appropriate, a Use and Exposure category, for use in the manufacturer’s, importer’s or DU’s CSA (Article 37 (1,2)) [1]. For registered substances, the manufacturer, importer or DU shall extend the CSA to include the new use within one month of receiving the request (Article 37 (3)) [1]. It is advisable that the DU informs his supplier verbally in advance about the request, as the allowed time-window of only one month is barely sufficient to make the necessary steps to include the new use in the CSA.

Where the manufacturer, importer or DU, having assessed the use, is unable to include this as an identified use, for reasons of protection of human health or the environment, he shall provide the Agency and the DU with the reason(s) for the decision in writing without delay. The supplier shall no longer supply his customers with the substance on its own or in a mixture without informing about the uses he advises against Article 37 (3) [1].

Alternatively if the DU wants to keep a specific use secret, he can create his own CSR within 12 months of receiving the SDS if the substance is already registered (Article 37 (4)) [1].

Then the DU is requested to report to the ECHA within a period of 6 months the new use (Article 38 (1)). There is no need to create a CSR and to notify the ECHA if the substance is used in volumes <1t/a.

As part of the on-site operational risk assessment, in accordance with the Hazardous Substances directive, the data given in the SDS and where applicable, the ES, must be considered in order to derive suitable RMM for the site and to check the effectiveness of these measures. Supporting data for the assessment of the effectiveness of RMM for inhalable exposure can be found in the SDS in Section 8 “exposure controls/personal protection”, in the form of control parameters such as OEL (Occupational Exposure Limit) and DNEL (Derived No Effect Level) and in the ES Section 6.1 “RMM related
to human health for workers or consumers”. The DNEL is the derived level of exposure below which no effects on human health are expected to occur.

Even if the particular use is not specifically mentioned in the ES, the ES can in principle, still cover it. If the conditions of use differ from those listed in the ES, scaling tools can be used in order to show that by varying the individual parameters (volume, concentration, temperature, frequency), this use is effectively covered within the terms of the ES.

The compliance check on RMM required by Article 37 (5) does not replace measuring the exposure for different uses. Workplace measurements e.g. for inhalable exposure are required, regardless of full compliance with the conditions of use, including RMM, that are set out in the SDS.

The following flow chart shows the sequence of actions that can be taken upon receipt of an e-SDS to perform a compliance check on proposed uses.

**Image 1: Flow chart in order to check conformity on uses [13]**

The risk characterisation in the context of CSR focuses on the comparison of the exposure to humans to the derived no effect level (DNEL). If the DNEL is maintained, there is no risk to human health and therefore no further measures are required.

The producer of sintered parts is required under Article 34 [1] to communicate to his supplier if he has new information on hazardous properties or any other information that might call into question the appropriateness of the risk management measures stated in the SDS for identified uses.

For producers of sintered parts a major challenge is the use of Nickel powder with regard to the inhalable exposure. The Generic Exposure Scenario 9 (GES) of Nickel metal is regularly revised. To accommodate not only estimated exposure values, but also real, process-related data from the industry in the ES, it is recommended that producers of sintered parts submit the results of their workplace measurements to the
European Powder Metallurgy Association (EPMA). The EPMA collects the results and passes data, made anonymous, to the Nickel-Institute, through which the data can be introduced to the appropriate consortium.

In the current GES 9 the estimated exposure for Nickel for the process “Mixing of nickel and other metallic powders” (scenario 9,1) is 0.1mgNi/m³ for the inhalable fraction of Nickel metal. Real data from industry however, indicates that this estimate is too low if no additional RMM with the aim of dust reduction have been implemented. This will be corrected in the next revision of the GES 9.

4. Relationship of DNEL to the „Arbeitsplatzgrenzwert“ (AGW)

The AGW is a legally binding occupational exposure limit for employers in Germany. The DNEL for inhalable and respirable dust are an aid to the assessment whether the implemented RMM are sufficient, provided that no AGW is available.

If the AGW is stricter than the DNEL, the company needs to comply with the AGW. If the DNEL is stricter than the AGW, then the level of the AGW needs to be reviewed by the ‘Ausschuss für Gefahrstoffe’ (AGS). If no AGW is available, only a DNEL, then the DNEL should serve as a benchmark, which should be taken into account during the on-site risk assessment and effectiveness check [14].

5. The use of Nickel-metal powder for PM part production processes

In Europe the typical Ni content for sintered parts is between 1.75% and 4% nickel. In high alloyed steels the Ni content is typically 12%, however in highly thermal and/or corrosively loaded materials Ni can be the base element of the alloy in concentrations of >50%. Depending on the alloying method in chemical and diffusion alloyed grades, nickel can be present in elementary bonded form or in solid solution as in pre-alloyed powder grades. When considering the dust exposure of nickel it is irrelevant in which form Nickel is present in the powder mix; elementary, i.e. 100%Ni or pre-alloyed, e.g. 1.9% Ni. The reason for this is that no toxicological studies on the effects of nickel in solid solution form are available. Depending on the alloying method and powder preparation the particle size of nickel is considered to be more or less the critical parameter in terms of inhalation exposure.

5.1 Classification of nickel-metal

The classification of Nickel-metal powder (CAS 7440-02-0) is the following:

H351: Suspected of causing cancer, category 2
H372: Causes damage to organs through prolonged or repeated exposure, category 1
H317: May cause an allergic skin reaction, category 1
H412: Harmful to aquatic life with long lasting effects, chronic category 3

Nickel-metal is listed in Annex XVII in item 27 as a substance with restrictions on uses. Generally PM part producers are not affected by the listed restrictions on uses, also chapter 3.3.
5.2 Aerodynamic diameter ($D_{\text{AE}}$) and “real” Nickel particle size ($D_{\text{Ni}}$)

The aerodynamic diameter is defined as diameter of a sphere with the normalized density of 1g/cm³, which has the same settling velocity in still or irrotational flowing air as the particle itself. All particles with an aerodynamic diameter of $D_{\text{AE}}<100\mu$m belong to the inhalable dust fraction. All particles with an aerodynamic diameter of $D_{\text{AE}}<4\mu$m belong to the respirable dust fraction.

$D_{\text{AE}}$ can be calculated with the following equation:

$$D_{\text{AE}} = \left(\frac{\rho_{\text{Ni}}}{\rho_{\text{Ni}}}\right)^{1/2} \times D_{\text{Ni}}$$

$\rho_{\text{Ni}} = \text{theoretical density of Nickel (8.9g/cm}^3\text{)}$

$D_{\text{Ni}} = \text{‘real’ diameter of a Nickel particle}$

It follows from the above equation that all Nickel particles with a ‘real’ diameter of $<33\mu$m belong to the Inhalable dust fraction and Nickel particles with a ‘real’ diameter of $<1.34\mu$m belong to the Respirable fraction.

Image 2 shows the particle size distribution of Carbonyl-Nickel, which is typically used in the PM industry.

Image 2: Particle size distribution of Carbonyl-Nickel 123 (Vale)

For the above shown specific powder lot of Ni 123 this indicates that about 92% of all Nickel particles are inhalable and just 1.5% of the particles are respirable. The contents of the two fractions can slightly vary from powder lot to powder lot.

5.3 Discussion on exposure levels for the inhalable and respirable fraction of Nickel-metal

In the Exposure Scenario (ES) for the uses of powder metallurgy the DNEL for nickel-metal is 0.05 mgNi/m³ for the inhalable dust fraction. This limit is 1/10 of the AGW of 0.5 mgNi/cm³, which was valid until 2004, in Germany.

In the ES the DNEL for the respirable fraction is 0.01mgNi/m³. Up to now, no AGW is available for the respirable fraction.
In 2009, the Scientific Committee on Occupational Exposure Limits (SCOEL) suggested a considerably lower OEL of 0.01 mgNi/m³ for the inhalable fraction (which is 1/50 of the former AGW) [15]. As a result of new findings from animal testing regarding the carcinogenicity of nickel metal, a limit for the respirable fraction is no longer included by SCOEL in the recommendation of OELs in June 2011 for the inhalable fraction. These studies were conducted on rats and show that respirable nickel particles produce no cancer in rats. Despite this, they are toxic [16]. With regard to these experiments, in June 2011 SCOEL recommended an OEL of 0.005 mgNi/m³ for the respirable fraction.

Currently, for Ni-metal there is no valid AGW (occupational exposure limit on national level) available in Germany. New limits are in discussion by the AGS (“Ausschuss für Gefahrstoffe” = Committee on Hazardous Substances). The AGS is actually proposing the limit for the respirable fraction to be 0.002 mgNi/cm³. At what stage binding OELs will be available on national (AGW) and European level (OEL) is not clear at the present time.

In Table 1 the statutes of current threshold limit discussions on national and European level is documented

<table>
<thead>
<tr>
<th>Threshold limits</th>
<th>Information</th>
<th>Actual situation</th>
<th>Inhalable Ni-metal (mg/m³)</th>
<th>Respirable Ni-metal (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGW*</td>
<td>AGS for Germany TRGS 900 legally binding limit in Germany expected to get into law 2012/2013</td>
<td>Old AGW of 0.5 was discarded in 2004 since then no value available</td>
<td>not available</td>
<td>currently discussed limit 0.002</td>
</tr>
<tr>
<td>DNEL** REACH!</td>
<td>Ni-industry (producers, SIEFs) for EU member states registration dossier, e-SDS, ES required in order to check and demonstr. safe use</td>
<td>0.05</td>
<td>0.01</td>
<td></td>
</tr>
<tr>
<td>OEL* (IOEL and BOEL)</td>
<td>SCOEL for EU member states OEL lists of SCOEL legally binding limit on EU level expected to get into law 2013/2014</td>
<td>suggestion in 2009 0.01 since 2011 no value available</td>
<td>suggestion in 2011 0.005</td>
<td></td>
</tr>
</tbody>
</table>

*AGW and OELs: Based on published scientific documentation; international body of experts; process open to external scrutiny

DNEL**: Recommendation of commercial contractor; based on in-house expertise of Ni industry

Table 1: National and European Occupational Exposure Limits for Nickel-metal

The lowering of the limits for nickel dust is not a result of REACH. Efforts to reduce the limits began in 2004, before the REACH regulation entered into force.

The development of exposure limits for other listed elements under examination by the AGS [17] for which currently no valid AGW is available (like Cobalt, Tungsten, Molybdenum, Titanium and Manganese) needs to be observed.

6. Nickel-dust measurements at the workplace

Workplace measurements should be based on personal exposure (not individual stations) and performed over the duration of one shift length, typically 8 hours. Both the inhalable dust and the respirable dust need to be determined as an 8h average
value. The total dust and nickel dust exposure should be determined for all uses described in GES 9 for Powder Metallurgy, see chapters 1.9 to 6.9. A company who is accredited to perform such measurements should carry out the measurements.

It is important to choose the appropriate measurement method. The initial recommendation of the Nickel Producers Environmental Research Association (NiPERA) in collaboration with the Institute of Occupation Medicine (IOM) was the use of the modified 8-stage Marple Cascade Impactor. This method however was proven not to be suitable for the processes of PM part producers by in-house measurements performed at GKN Sinter Metals. The reason is that the amount of dust that was collected in the duration of 8h was too small to ensure a statistically valid result in the gravimetric analysis. Therefore we switched to another method of personal measurement, called PGP-GSP 3,5 for the inhalable fraction and PGP-FSP 2 for the respirable fraction. The Institute of Occupational Health and social accident Insurance (IFA) in Germany developed this measuring method. Both dust sampler heads can be operated with a rate of 10 l/min, which increases the confidence level of the measured values.

In diagrams 1 and 2, the measured values for the inhalable and respirable fractions of Nickel are summarised. The documented values below were obtained in 2011 at the European sites of GKN Sinter Metals for nickel-metal, before introducing additional RMM for dust reduction.

![Diagram 1](image)

**Diagram 1: Personal dust measurements of the inhalable fraction of Nickel-metal**

Diagram 1 shows that the measured values for parts of the powder mixing process and the powder compaction are well above the DNEL of 0,05mgNi/m³. This indicates that without implementing additional RMM, safe use of Nickel cannot be demonstrated for the processes mentioned above. Safe use is given if the Risk Characterisation Ratio (RCR) is <1.
RCR = measured value/DNEL

RCR < 1 use is considered as safe use
RCR > 1 use is not considered as safe, the implementation of additional RMM is required.

Diagram 2: Personal dust measurements of the respirable fraction of nickel-metal

6.1. Conclusions of the nickel dust measurements at GKN Sinter Metals

GKN Sinter Metals complies with the former AGW of 0.5mgNi/m³ for the inhalable fraction of nickel-metal for all manufacturing processes.

The DNELs established in the ES for the PM-processes of powder mixing and powder compaction with respect to the inhalable and respirable fraction of nickel dust are challenging. It is easier to prove safe use for the respirable fraction of nickel powder than for the inhalable fraction. The implementation of the RMM advised in GES 9 is essential.

7. Measures to reduce Nickel dust in the workplace of PM part producers

Using the following RMM, the Nickel dust concentration can be minimized in the workplace:

- Intensive wet cleaning
- Enclosure around mixers/powder presses
- Additional central and local exhaust ventilation
Automated folding of empty big-bags, using an extruder in a closed container with extraction
Sealing and LEV for all powder pouring processes

The costs of implementing these measures are potentially enormous. If on a national (AGW) or European level (OEL) limits below the DNEL need to be enforced, then temporary use of respiratory protective equipment (FFP3 masks are recommended) for operations with the highest dust exposure is obligatory.

In addition nickel dust exposure in the workplace can be reduced by decreasing the nickel content in the alloy or by complete substitution of the Nickel. The development and establishment of suitable alloy systems, which do not necessarily replace the potential risks of Nickel through other hazards, takes time. The development of the occupational exposure limits of new alloying elements, which are options to replace Nickel, such as Cr, Mn and Si, must be considered, see section 5.3. The substitution of Nickel may require new furnace technology, as sintering temperature and atmosphere need to be adapted to the sintering behaviour of the new alloying elements.

In parallel, efforts are taken by all powder manufacturers to improve powder preparation techniques (e.g. agglomeration, bonding) in order to reduce dusting of Ni containing powder grades.

To monitor the effectiveness of implemented RMM, in-house dust measurements are useful. When purchasing appropriate in-house dust measuring equipment, an additional benefit is that it also enables the evaluation of powder developments with the aim of dust reduction. So, GKN Sinter Metals has purchased the personal related dust-measuring instrument Respicon TM, produced by Hund Wetzlar. The Respicon TM is a combined gravimetric/photometric device to measure the inhalable, thoracic and respirable dust fraction. The instrument includes one optical measuring chamber for scattered light in each filter stage for the direct measurement of the dust concentration over time. For weighing the collected dust of each filter a microbalance with a sensitivity of 0.01-0.001mg is required. Chemical analysis on the dust collected on the filters can be performed if desired.

8. Socio-economic analysis on nickel powder

In the SEA report it is assumed that Ni-exposures below 0.05 mg Ni/m$^3$ for the inhalable fraction will carry no risk for human health. Considering that in most workplaces about 10% of the total aerosol is in the respirable fraction, it must be assumed that the respirable value of 0.005 mgNi/m$^3$ will carry no risk to human health [19]. In the conclusions of the SEA report [20] it is described that on the basis of available evidence, there is no demonstrable substantial benefit in the reduction of the Occupational Exposure Level (OEL) for Nickel to 0.01mgNi/m$^3$ (inhalable fraction) as proposed by SCOEL. The examined costs to comply with the proposed OELs are out of proportion to the potential health benefits that workers exposed to nickel dust might receive.

The costs estimated to comply with the proposed OEL < DNEL considering the sector of PM industry are with 7,736 Euro/ton the highest, which would lead to the largest
rate of price increases compared to the other industry sectors considered in the SEA [21].

However, it is likely that the SEA is not considered when fixing the OEL by the European authorities. The reason for this is that SEA is normally taken into account only for substances that are classified as carcinogens. Currently, however, this is not the case, at least for the respirable fraction of nickel-metal. As a consequence, for the respirable fraction of nickel-metal an indicative OEL (IOEL) must be expected. SEA however is only considered when determining binding OELs (BOEL) [22].

9. Communication in the supply chain

REACH requires communication along the supply chain in both directions, to the supplier and to the purchaser.

It is advisable for producers of PM parts to require suppliers and subcontractors (e.g. for heat treating, machining companies, coatings etc.) to make a commitment to be REACH compliant. This commitment should include an agreement to perform the following duties:

- In accordance with Article 5 [1], substances on their own, in mixtures or in articles supplied, with respect to volumes and classification, shall be duly registered in good time with consideration of the uses of the company being supplied. The supplier/subcontractor is required to communicate information about the status of the registration, especially if it can be foreseen that the substance cannot be registered in due time
- According to Article 31 and 32 [1] an up-to-date SDS and safety information (SI) have to be provided
- To inform the PM parts producer if a request for authorisation was granted or denied and to inform as soon as possible if substitution of a substance/mixture is required
- To inform the PM parts producer if SVHC candidates, with respect to the latest update of the SVHC list, are present in the supplied articles or packaging in concentrations >0.1% and to submit information about safe use of the article

In a REACH standard letter the purchaser of PM parts needs to be informed:

- About the presence of SVHC candidates in the delivered article in concentrations >0.1% with reference to the most current status of the SVHC-list
- About conformity in terms of substances listed in Annex XIV and XVII and where applicable, the activities required for the substitution of suspect substances on their own or in a mixtures
- About collaboration with trade associations with the aim that all uses of the PM technology are considered in a harmonised way in registration dossiers
- About compliance in terms of required registration and notification at the ECHA if substances are intentionally released from articles
10. **Inventory list of substances**

The compilation of inventory lists of substances and volumes is not required by the REACH regulation [23]. However, to meet the obligations mentioned in section 3, the presence of these lists is a recommended tool. All raw materials, additives and operating materials i.e. powder, powder additives, material for plastic infiltration and coatings, including all media which are in contact with the produced articles during production such as sizing oils, cooling fluids, cleaning agents, quenching media and corrosion inhibitors need to be captured for each legal business entity. Compiling data on volumes per year for each substance as a three year average value is required in order to find out if, for example, a SVHC candidate needs to be notified at the ECHA.

The inventory lists of GKN Sinter Metals include the following information (not necessarily complete: it is also possible to include additional information):

- Name and article number of the product/substance for clear identification
- Identification of the received product as a substance, a mixture, an intermediate or an article
- Identification of the producer, supplier or subcontractor
- Yearly consumption as an average value of the last three years for each supplier
- Origin country of the invoice (EU or non-EU?)
- Date of the latest issue of the SDS available
- Classification of the substance/mixture
- Occupational exposure limits e.g. Derived No Effect Level (DNEL), predicted No Effect Concentration (PNEC), Arbeitsplatzgrenzwert (AGW), OEL in accordance with the SDS
- Constituent substances classified as hazardous, CAS-, EINECS-, EG-, Registration Number if available, classification and concentration
- Compliance check in terms of the intended use compared to the identified uses listed in the SDS or if available in the ES
- Comparison of implemented RMM on-site compared to advised RMM in the SDS
- Definition of the role in the supply chain the company has for each product (DU or Importer)
- Is the substance/mixture intentionally released from the articles produced?
- Are substances included in the product, which are listed in the SVHC-list or in Annex XIV; information about concentration levels
- Is a substance included with restrictions on uses (Annex XVII)? Does this affect the intended use?
- Is substitution of the product required?
- Notes regarding the contents and key points arising from direct communication with the supplier
• Which REACH obligations will need to be implemented in practice as result of all points mentioned above

It is doubtful whether, in the long term, individual lists of substances are the most appropriate tool to control, document and prove REACH compliance, as a huge number of substances connected to a wide variety of uses need to be observed. There is also other legislation besides REACH that must be considered, e.g.:

- ROHS I and II: Directive 2002/95/EC and 2011/65/EC
- US Conflict Mineral Law form July 2010 (Dodd Frank Act)
- Ecological and environment protection requirements e.g. Life Cycle Assessment (LCA) and Recycling, Reuse, Recovery (RRR)

Additionally, following up the continuous updates and expansions to the different legislation make compliance checks very complex. Software to check and prove legal compliance is available on the market. However, it is not yet clear whether these can successfully cover all requirements.

11. **REACH Enforcement**

Within the scope of REACH-en-Force 1, in the period 2009-2011 approximately 2400 companies have been inspected in Europe, of which 440 were located in Germany. The focus of REACH-en-Force 1 was the monitoring of the pre-registration and registration obligations for manufacturers and importers of substances and the ensuring the presence of REACH compliant SDS [24].

In 2009, deviations were found for 20% of all inspected companies in Germany. In 2010/2011 this number was only 8%. The controlling authority has come to the conclusion that the industry has made efforts towards and is willing to comply with the regulation. However, the following criticisms were made:

- REACH is given too little attention by some companies
- Some SDS only partially meet requirements for REACH compliance
- Internal company network between purchasing, production, occupational health and safety and the protection of the environment need to be improved with regard to REACH
- Companies rely too heavily on technical and/or organisational tools. The communication about hazards and risks within the company and the supply chain needs to be improved. [25]

As part of REACH-en-Force 2, the REACH- and CLP- (Classification, Labelling and Packaging) duties of DU, who produce formulations, are inspected. This enforcement started in 2011. 180 reviews should have been completed by the end of March 2012.

REACH-en-Force 3 was planned for 2012. The aim of this enforcement is to review the collaboration of the enforcement authorities with customs. [26]
Currently it is claimed that the enforcement activities in the member states differ in intensity and frequency. The interpretation of the legal text and the guidelines for enforcement show differences in practical implementation. Both the industry and the enforcement authorities are currently in a process of learning. Procedures, communication tools and IT systems must be developed in order to ensure that REACH is implemented successfully. Where uniform enforcement cannot be realised due to differences in country-specific organisation and jurisdiction, harmonisation should be pursued in order to achieve identical conditions for companies in all member states. This is one of the main tasks of the Enforcement Forum of the REACH- and CLP-legislation, which was built by the ECHA [27].

For manufacturers of PM parts close collaboration with national and international organisations and authorities (FPM, WSM, WVM, EPMA, Nickel Institute, BAuA, BG, etc.) is required for timely identification of our risks and last but not least to represent the interests of our branch of industry.

“Things are never as they are.
They are always what you make of them”
Jean Marie Lucien Pierre Anouilh (*1910 † 1987)

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Glossary

AGS  Ausschuss für Gefahrstoffe
AGW  Arbeitsplatzgrenzwert
BOEL  Binding Occupational Exposure Limit
CLP  Classification, Labelling and Packaging (regulation)
CSR  Chemical Safety Report
DNEL  Derived No Effect Level
DU  Downstream User
ECHA  European Chemical Agency
ELOC  Equivalent Level Of Concern
ELV  End of Life Vehicle (directive)
EPMA  European Powder Metallurgy Association