Chapter 1

Introduction

The RAKIP Markup Language (RakML) is an XML-based format for the description of model metadata.
...

Chapter 2

Technical specification

2.1 Primitive data types

The primitive data types used in RAKIP-ML are taken from the XML Schema 1.0 including: **string**, **boolean**, **int** and **date**.

2.2 General structure

Every RAKIP model involves four main metadata components: general information, scope, data background and model math. A RAKIP-ML document has one model with these components.

2.3 Common types

2.3.1 Assay

Element	Type	Min. Ocurrences	Max. Ocurrences
Name	string	1	1
Description	string	0	1
MoisturePercentage	string	0	1
FatPercentage	string	0	1
DetectionLimit	string	0	1
QuantificationLimit	string	0	1
LeftCensoredData	string	0	1
ContaminationRange	string	0	1
UncertaintyValue	string	0	1

Name A name given to the assay.

Description General description of the assay. Corresponds to the Protocol REF in ISA.

MoisturePercentage Percentage of moisture in the original sample.

FatPercentage Percentage of fat in the original sample.

DetectionLimit Limit of detection reported in the unit specified by the variable "Hazard Unit".

QuantificationLimit Limit of quantification reported in the unit specified by the variable "Hazard Unit".

LeftCensoredData Percentage of measures equal to LOQ and/or LOD.

ContaminationRange Range of result of the analytical measure reported in the unit specified by the variable "Hazard unit".

UncertaintyValue Indicate the expanded uncertainty (usually 95% confidence interval) value associated with the measurement expressed in the unit reported in the field "Hazard unit".

Listing 2.1: Example of Assay

```
<Name>Bradford protein assay</Name>
<Description>spectroscopic analytical procedure used to measure
    the concentration of protein in a solution. It is subjective,
    i.e., dependent on the amino acid composition of the
    measured protein.
</Description>
<DetectionLimit>30−300</DetectionLimit>
<QuantificationLimit>5000 − 8000</QuantificationLimit>
<ContaminationRange>500−4000</ContaminationRange>
```

2.3.2 Contact

Element	Type	Min. Ocurrences	Max. Ocurrences
Title	string	0	1
FamilyName	string	0	1
GivenName	string	0	1
Email	string	1	1
Telephone	string	0	1
StreetAddress	string	0	1
Country	string	0	1
City	string	0	1
ZipCode	string	0	1
Region	string	0	1
TimeZone	string	0	1
Gender	string	0	1
Note	string	0	1
Organization	string	0	1

Listing 2.2: Example of Contact

```
<Title>Dr.</Title>
<FamilyName>Romanov</FamilyName>
<GivenName>Natalia</GivenName>
<Email>black_widow@marvel.com</Email>
<Telephone>030 12345</Telephone>
<StreetAddress>Nahmitzer Damm 40</StreetAddress>
<Country>Russian Federation</Country>
<City>Berlin</City>
<Region>Berlin−Brandenburg</Region>
<Organization>SHIELD</Organization>
```

2.3.3 Exposure

Element	Type	Min. Ocurrences	Max. Ocurrences
Type	string	1	1
UncertaintyEstimation	string	0	1
MethodologicalTreatmentOfLeftCensoredData	string	0	*
LevelOfContaminationAfterLeftCensoredDataTreatment	string	0	*
Scenario	string	0	*

Type Type of the exposure

UncertaintyEstimation Analysis to estimate uncertainty

MethodologicalTreatmentOfLeftCensoredData describe the mathematical method to replace left-censored data: recommandation of WHO (2013), distribution or ohters

LevelOfContaminationAfterLeftCensoredDataTreatment describe the range of of the level of contamination after left censored data treatment

Scenario describe the different scenario of exposure assessment

2.3.4 Hazard

Element	Type	Min. Ocurrences	Max. Ocurrences
Type	string	0	1
Name	string	1	1
Description	string	0	1
Unit	string	0	1
AdverseEffect	string	0	1
SourceOfContamination	string	0	1
BenchmarkDose	string	0	1
MaximumResidueLimit	string	0	1
NoObservedAdverseAffectLevel	string	0	1
AcceptableOperatorExposureLevel	string	0	1
AcuteReferenceDose	string	0	1
AcceptableDailyIntake	string	0	1
IndSum	string	0	1

Type General classification of the hazard for which the model or data applies.

Name Name of the hazard for which the model or data applies.

Description Description of the hazard for which the model or data applies.

Unit Unit of the hazard for which the model or data applies.

AdverseEffect Morbidity, mortality, origin.

SourceOfContamination Source of contamination, origin.

BenchmarkDose A dose or concentration that produces a predetermined change in response rate of an adverse effect (called the benchmark response or BMR) compared to background.

MaximumResidueLimit International regulations and permissible maximum residue levels in food and drinking water.

NoObservedAdverseAffectLevel Level of exposure of an organism, found by experiment or observation, at which there is no biologically or statistically significant increase in the frequency or severity of any adverse effects in the exposed population when compared to its appropriate control.

LowestObservedAdverseAffectLevel Lowest concentration or amount of a substance found by experiment or observation that causes an adverse alteration of morphology, function, capacity, growth, development, or lifespan of a target organism distinguished from normal organisms of the same species under defined conditions of exposure.

AcceptableOperatorExposureLevel Maximum amount of active substance to which the operator may be exposed without any adverse health effects. The AOEL is expressed as milligrams of the chemical per kilogram body weight of the operator.

AcuteReferenceDose An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for an acute duration (24 hours or less) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

AcceptableDailyIntake Measure of amount of a specific substance in food or in drinking water tahta can be ingested (orally) on a daily basis over a lifetime without an appreciable health risk.

IndSum Define if the parameter reported is an individual residue/analyte, a summed residue definition or part of a sum a summed residue definition.

Listing 2.3: Example of Hazard

```
<Type>Organic contaminants</Type>
<Name>Norovirus (Norwalk−like virus)</Name>
<Description>norovirus is described as nast and hard to get rid
of</Description>
<Unit>CFU</Unit>
<AdverseEffect>morbitity</AdverseEffect>
<SourceOfContamination>sewage</SourceOfContamination>
<MaximumResidueLimit>0.01 mg/kg</MaximumResidueLimit>
<NoObservedAdverseAffectLevel>10 mg</NoObservedAdverseAffectLevel>
<LowestObservedAdverseAffectLevel>40 mg</LowestObservedAdverseAffectLevel>
<AcceptableOperatorExposureLevel>50 mg</AcceptableOperatorExposureLevel>
<AcuteReferenceDose>80 mg</AcuteReferenceDose>
<AcceptableDailyIntake>20 mg</AcceptableDailyIntake>
```

2.3.5 Laboratory

Element	Type	Min. Ocurrences	Max. Ocurrences
Accreditation	string	0	1
Name	string	0	1
Country	string	0	1

Accreditation The laboratory accreditation to ISO/IEC 17025.

Name Laboratory code (National laboratory code if available) or Laboratory name

Country Country where the laboratory is placed. (ISO 3166-1-alpha-2).

Listing 2.4: Example of Laboratory

```
<Accreditation>Accredited</Accreditation>
<Name>National High Magnetic Field Laboratory</Name>
<Country>United States</Country>
```

2.3.6 ModelCategory

Element	Type	Min. Ocurrences	Max. Ocurrences
ModelClass	string	1	1
ModelSubClass	string	0	1
ModelClassComment	string	0	1
BasicProcess	string	0	1

ModelClass   Type of model used to build-up the risk assessment structure.

ModelSubClass   Sub-cassification of the model given the Model Class

BasicProcess   Defines the impact of the specific process on the hazard

Listing 2.5: Example of ModelCategory

```
<ModelClass>Dose−response model</ModelClass>
<ModelClassComment>This Model Class is very special</ModelClassComment>
```

2.3.7   ModelEquation

Element	Type	Min. Ocurrences	Max. Ocurrences
Name	string	1	1
Class	string	0	1
ModelEquation	string	1	1
Reference	string	1	1
ModelHypothesis	string	0	*

Name   A name given to the model equation

Class   Information on that helps to categorize model equations

ModelEquation   The pointer to the file that holds the software code (e.g. R-script)

Reference   Information on the source, where the equation has been extracted from - if available

2.3.8   Parameter

Element	Type	Min. Ocurrences	Max. Ocurrences
Id	string	1	1
Classification	string	1	1
Name	string	1	1
Description	string	0	1
Unit	string	1	1
UnitCategory	string	0	1
DataType	string	0	1
Source	string	0	1
Subject	string	0	1
Distribution	string	0	1
Value	string	0	1
Reference	Reference	0	*
VariabilitySubject	string	0	1
MinValue	string	0	1
MaxValue	string	0	1
Error	string	0	1

Id   An unambiguous and sequential ID given to the parameter. To be compatible with SBML, only letters from A to Z, numbers and "_" are acepted for ID creation.

Classification   General classification of the parameter (e.g. Input, Constant, Output...).

Name   A name given to the parameter.

Description   General description of the parameter.

Unit   Unit of the parameter.

UnitCategory   General classification of the parameter unit.

DataType   Information on the data format of the parameter, e.g. if it is a categorial variable, int, double, array of size x,y,z.

Source   Information on the type of knowledge used to define the parameter value.

Subject   Scope of the parameter, e.g. if it refers to an animal, a batch of animals, a batch of products, a carcass, a carcass skin etc.

Distribution   Information on the distribution describing the parameter (e.g. variability, uncertainty, point estimate...) .

Value   Numerical value of the parameter. A default value is mandatory (needs to be provided) for each of the the "Input parameters". If the parameter value is provided in a file, the path of the file needs to be provided.

Reference   Information on the source, where the value of the parameter has been extracted from - if available. The format should use that used in other "Reference" metadata. Preferably DOI.

VariabilitySubject   Information "per what" the variability is described. It can be variability between broiler in a flock, variability between all meat packages sold in Denmark, variability between days, etc.

MinValue   Numerical value of the minimum limit of the parameter that determines the range of applicability for which the model applies

MaxValue   Numerical value of the maximum limit of the parameter that determines the range of applicability for which the model applies

Error   Error of the parameter value.

Listing 2.6: Example of Parameter

```
<Id>Dose_matrix</Id>
<Classification>input</Classification>
<Name>Dose_matrix</Name>
<Description>matrix with GEC NoV for each serving (rows=servings;
    columns = number of different employee−teams that prepare food)
</Description>
<Unit>Others</Unit>
<UnitCategory>Other</UnitCategory>
<DataType>matrixOfNumbers</DataType>
<Source>Article</Source>
<Subject>Animal</Subject>
<Distribution>Bernoulli 1</Distribution>
<Value>as.matrix(read.table(file =\"Dose_matrix.csv\",sep=\",\",
    header = TRUE, row.names=1))</Value>
<VariabilitySubject>days</VariabilitySubject>
<MinValue>10000.0</MinValue>
<MaxValue>0.0</MaxValue>
<Error>0.5</Error>
```

2.3.9 PopulationGroup

Element	Type	Min. Ocurrences	Max. Ocurrences
Name	string	1	1
TargetPopulation	string	0	1
PopulationSpan	string	0	*
PopulationDescription	string	0	*
PopulationAge	string	0	*
PopulationGender	string	0	1
BMI	string	0	*
SpecialDietGroups	string	0	*
PatternConsumption	string	0	*
Region	string	0	*
Country	string	0	*
PopulationRiskFactor	string	0	*
Season	string	0	*

Name   Name of the population for which the model or data applies

TargetPopulation   population of individual that we are interested in describing and making statistical inferences about

PopulationSpan   Temporal information on the exposure duration

PopulationDescription   Description of the population for which the model applies (demographic and socio-economic characteristics for example). Background information that are needed in the data analysis phase: size of household, education level, employment status, professional category, ethnicity, etc.

PopulationAge   describe the range of age or group of age

PopulationGender   describe the percentage of gender

BMI   describe the range of BMI or class of BMI or BMI mean

SpecialDietGroups   sub-population with special diets (vegetarians, diabetics, group following special ethnic diets)

PatternConsumption   describe the consumption of different food items: frequency, portion size

Region   Spatial information (area) on which the population group of the model or data applies

Country   Country on which the population group of the model or data applies

PopulationRiskFactor   population risk factor that may influence the outcomes of the study, confounder should be included

Season   distribution of surveyed people according to the season (influence consumption pattern)

Listing 2.7: Example of PopulationGroup

```
<Name>human consumer, no age specification</Name>
<TargetPopulation>seniors</TargetPopulation>
<PopulationDescription>
    80% are considered susceptible to infection
</PopulationDescription>
```

```
<PopulationGender>50% male</PopulationGender>
<BMI>18.5 − 24.9</BMI>
<SpecialDietGroups>love cake</SpecialDietGroups>
<Region>Madrid</Region>
<Country>Spain</Country>
<PopulationRiskFactor>low physical activity</PopulationRiskFactor>
<Season>spring</Season>
```

2.3.10   QualityMeasures

Element	Type	Min. Ocurrences	Max. Ocurrences
SSE	double	0	1
MSE	double	0	1
RMSE	double	0	1
RSquared	double	0	1
AIC	double	0	1
BIC	double	0	1

Listing 2.8: Example of QualityMeasures

```
<SSE>0.0</SSE>
<MSE>0.2</MSE>
<RMSE>0.3</RMSE>
<RSquared>0.9</RSquared>
<AIC>0.0</AIC>
<BIC>1.0</BIC>
```

2.3.11   Reference

Element	Type	Min. Ocurrences	Max. Ocurrences
IsReferenceDescription	boolean	1	1
Type	string	0	1
Date	string	0	1
Pmid	string	0	1
Doi	string	0	1
AuthorList	string	0	1
Title	string	1	1
Abstract	string	0	1
Journal	string	0	1
R Volume	int	0	1
Issue	int	0	1
Status	string	0	1
Website	string	0	1
Comment	string	0	1

IsReferenceDescription   Indicates whether the publication serves as the reference description for the model.

Type   Type of the publication. Takes a value from the reserved words listed at 2.1.

Year   Temporal information on the publication date.

Pmid   The PubMed ID related to this publication.

Doi   The DOI related to this publication.

AuthorList   Name and surname of the authors who contributed to this publication.

ABST	CHAP	DICT	GEN	MANSCPT	PCOMM	VIDEO
ADVS	CHART	EBOOK	GOVDOC	MAP	RPRT	
AGGR	CLSWK	ECHAP	GRANT	MGZN	SER	
ANCIENT	COMP	EDBOOK	HEAR	MPCT	SLIDE	
ART	CONF	EDJOUR	ICOMM	MULTI	SOUND	
BILL	CPAPER	ELECT	INPR	MUSIC	STAND	
BLOG	CTLG	ENCYC	JOUR	NEW	STAT	
BOOK	DATA	EQUA	JFULL	PAMP	THES	
CASE	DBASE	FIGURE	LEGAL	PAT	UNPB	

Table 2.1: Publication types

Title Title of the publication in which the model or the data has been described.

Abstract Abstract of the publication in which the model or the data has been described.

Journal Publication journal.

Volume Publication volume.

Issue Publication issue.

Status Publication status.

Website Publication website.

Comment Publication comment.

Listing 2.9: Example of Reference

```
<IsReferenceDescription>true</IsReferenceDescription>
<Type>PAMP</Type>
<Date>3805−07−02</Date>
<Doi>10.1111/risa.12758</Doi>
<AuthorList>Jack Bauer, Kiefer Sutherland</AuthorList>
<Title>Quantitative Risk Assessment of Norovirus Transmission in Food Establishments:
    Evaluating the Impact of Intervention Strategies and Food Employee Behavior on
    the Risk Associated with Norovirus in Foods.
</Title>
<Abstract>
    This research looks at the work of Margaret C. Anderson, the editor of the
    Little Review. The review published first works by Sherwood Anderson, James
    Joyce, Wyndham Lewis, and Ezra Pound. This research draws upon mostly primary
    sources including memoirs, published letters, and a complete collection of the
    Little Review. Most prior research on Anderson focuses on her connection to the
    famous writers and personalities that she published and associated with. This
    focus undermines her role as the dominant creative force behind one of the most
    influential little magazines published in the 20th Century. This case example
    shows how little magazine publishing is arguably a literary art.
</Abstract>
<Status>Accepted</Status>
<Website>https://nature.com</Website>
<Comment>publisher demands edits</Comment>
```

2.3.12 SpatialInformation

Element	Type	Min. Ocurrences	Max. Ocurrences
Region	string	0	1
Country	string	0	1

Region Spatial information (area) on which the model or data applies.

Country Country on which the model or data applies.

Listing 2.10: Example of SpatialInformation

```
<Region>Bayern</Region>
<Country>Germany</Country>
```

2.3.13 Study

Element	Type	Min. Ocurrences	Max. Ocurrences
Identifier	string	0	1
Title	string	1	1
Description	string	0	1
DesignType	string	0	1
AssayMeasurementType	string	0	1
AssayTechnologyType	string	0	1
AssayTechnologyPlatform	string	0	1
AcreditationProcedureForTheAssayTechnology	string	0	1
ProtocolName	string	0	1
ProtocolType	string	0	1
ProtocolDescription	string	0	1
ProtocolURI	string	0	1
ProtocolParametersName	string	0	1
ProtocolComponentsName	string	0	1
ProtocolComponentsType	string	0	1

Identifier A user defined identifier for the study

Title A title for the Study.

Description A brief description of the study aims.

DesignType The type of study design being employed.

AssayMeasurementType The measurement being observed in this assay.

AssayTechnologyType The technology being employed to observe this measurement.

AssayTechnologyPlatform The technology platform used.

AccreditationProcedureForTheAssayTechnology Accreditation procedure for the analytical method used.

ProtocolName The name of the protocol, e.g.Extraction Protocol.

ProtocolType The type of the protocol, preferably coming from an Ontology, e.g. Extraction Protocol.

ProtocolDescription A description of the Protocol.

ProtocolURI A URI to link out to a publication, web page, etc. describing the protocol.

ProtocolParametersName   The parameters used when executing this protocol.

ProtocolComponentsType   The components used when carrying out this protocol.

Listing 2.11: Example of Study

```
<Identifier>Study_Generic_Sheet_1</Identifier>
<Title>Quantitative Risk Assessment of Norovirus Transmission in Food
    Establishments: Evaluating the Impact of Intervention Strategies
    and Food Employee Behavior on the Risk Associated with Norovirus
    in Foods.
</Title>
<Description>This Study will show, wether the FSK Lab will correctly
    read and run a generic and fully annotated model.
</Description>
<DesignType>Trial and Error</DesignType>
<AssayMeasurementType>It works or it doesn't</AssayMeasurementType>
<AssayTechnologyType>Anatomic−pathologic Tests</AssayTechnologyType>
<AssayTechnologyPlatform>Orbital Platform</AssayTechnologyPlatform>
<AccreditationProcedureForTheAssayTechnology>ISO/IEC17025
</AccreditationProcedureForTheAssayTechnology>
<ProtocolName>Extraction Protocol of FSK</ProtocolName>
<ProtocolType>Extraction Protocol</ProtocolType>
<ProtocolDescription>The protocol is definitely not made up</ProtocolDescription>
<ProtocolURI>https://url−for−study−protocol−location.bfr.bund.de</ProtocolURI>
<ProtocolVersion>version 1.0</ProtocolVersion>
<ProtocolParametersName>Parameter 1</ProtocolParametersName>
<ProtocolComponentsName>windows pc</ProtocolComponentsName>
<ProtocolComponentsType>hardware</ProtocolComponentsType>
```

2.3.14   StudySample

Element	Type	Min. Ocurrences	Max. Ocurrences
SampleName	string	1	1
ProtocolOfSampleCollection	string	1	1
SamplingStrategy	string	0	1
TypeOfSamplingProgram	string	0	1
SamplingMethod	string	0	1
SamplingPlan	string	1	1
SamplingWeight	string	1	1
SamplingSize	string	1	1
LotSizeUnit	string	0	1
SamplingPoint	string	1	1

SampleName   An unambiguous ID given to the samples used in the assay.

ProtocolOfSampleCollection   Additional protocol for sample and sample collection. Corresponds to the Protocol REF in ISA.

SamplingStrategy   Sampling strategy (ref. EUROSTAT - Typology of sampling strategy, version of July 2009).

TypeOfSamplingProgram   Indicate the type of programm for which the samples have been collected.
.

SamplingMethod   Sampling method used to take the sample.

SamplingPlan   description of data collection technique: stratified or complex sampling (several stages).

SamplingWeight description of the method employed to compute sampling weight (nonresponse-adjusted weight).

SamplingSize number of units, full participants, partial participants, eligibles, not eligible, unresolved (eligibility status not resolved)....

LotSizeUnit Unit in which the lot size is expressed.

SamplingPoint Point in the food chain where the sample was taken. (Doc. ESTAT/F5/ES/155 "Data dictionary of activities of the establishments").

Listing 2.12: Example of StudySample

```
<SampleName>Sample 1</SampleName>
<ProtocolOfSampleCollection>SampleID_1</ProtocolOfSampleCollection>
<SamplingStrategy>Convenient sampling</SamplingStrategy>
<TypeOfSamplingProgram>Diet study</TypeOfSamplingProgram>
<SamplingMethod>According to Reg 152/2009</SamplingMethod>
<SamplingPlan>Random sampling</SamplingPlan>
<SamplingWeight>description of the method employed to compute sampling
    weight (nonresponse−adjusted weight)
</SamplingWeight>
<SamplingSize>10000.0</SamplingSize>
<LotSizeUnit>log10(CFU/25g)</LotSizeUnit>
<SamplingPoint>Catering</SamplingPoint>
```

Chapter 3

GenericModel

3.1   GeneralInformation

Element	Type	Min. Ocurrences	Max. Ocurrences
Name	string	1	1
Source	string	0	1
Identifier	string	1	1
Author	Contact	1	1
Creator	Contact	1	1
CreationDate	date	1	1
ModificationDate	date	0	*
Rights	string	1	1
Available	string	0	1
Format	string	0	1
Reference	Reference	1	*
Language	string	0	1
Software	string	0	1
LanguageWrittenIn	string	0	1
ModelCategory	ModelCategory	0	1
Status	string	0	1
Objective	string	0	1
Description	string	0	1

Name   Name given to the model or data.

Source   A related resource from which the described resources is derived.

Identifier   An unambiguous ID given to the model or data.

Author   Person who generated the model code or generated the data set originally.

Creator   The person responsible for creating the model file in the present form or the person responsible for creating the data file in the present form.

CreationDate   Temporal information on the model creation date.

ModificationDate   Temporal information on the last modification of the model.

Rights   Information on rights held in and over the resource.

Available   Availability of data or model.

Format   Form of model or data (file extension).

Reference

Language   Language of the resource.

Software   Program in which the model has been implemented.

LanguageWrittenIn   Language used to write the model, e.g. R or Matlab.

ModelCategory

Status   Curation status of the model.

Objective   Objective of the model or data.

Description   General description of the study, data or model.

3.2   Scope

Element	Type	Min. Ocurrences	Max. Ocurrences
Product	Product	0	*
Hazard	Hazard	0	*
PopulationGroup	PopulationGroup	0	*
GeneralComment	string	0	1
TemporalInformation	string	0	—
1 SpatialInformation	SpatialInformation	0	1

3.2.1   Product

Element	Type	Min. Ocurrences	Max. Ocurrences
Name	string	1	1
Description	string	0	1
Unit	string	0	1
Method	string	0	1
Packaging	string	0	1
Treatment	string	0	1
OriginCountry	string	0	1
OriginArea	string	0	1
FisheriesArea	string	0	1
ProductionDate	date	0	1
ExpiryDate	date	0	1

Name   The product-matrix (animal, food product, matrix, lab media, etc.) for which the model or data applies

Description   Description of the product-matrix (animal, food product, matrix, lab media, etc.) for which the model or data applies

Unit   Units of the product-matrix for which the model or data applies

Method   Type of production for the product/ matrix

Packaging   Describe container or wrapper that holds the product/matrix. Common type of packaging: paper or plastic bags, boxes, tinplate or aluminium cans, plastic trays, plastic bottles, glass bottles or jars.

Treatment   Used to characterise a product/matrix based on the treatment or processes applied to the product or any indexed ingredient.

OriginCountry   Country of origin of the food/product (ISO 3166-1-alpha-2 country code).

OriginArea   Area of origin of the food/product (Nomenclature of territorial units for statistics – NUTS – coding system valid only for EEA and Switzerland).

FisheriesArea   Fisheries or aquaculture area specifying the origin of the sample (FAO Fisheries areas).

ProductionDate   date of production of food/product

ExpiryDate   date of expiry of food/product

3.3   DataBackground

Element	Type	Min. Ocurrences	Max. Ocurrences
Study	Study	0	1
StudySample	StudySample	0	*
DietaryAssessmentMethod	DietaryAssessmentMethod	0	*
Laboratory	Laboratory	0	*
Assay	Assay	0	*

3.3.1   DietaryAssessmentMethod

Element	Type	Min. Ocurrences	Max. Ocurrences
CollectionTool	string	0	1
NumberOfNonConsecutiveOneDay	string	0	1
SoftwareTool	string	0	1
NumberOfFoodItems	string	0	1
RecordTypes	string	0	1
FoodDescriptors	string	0	1

CollectionTool   food diaries, interview, 24-hour recall interview, food propensy questionnaire, portion size measurement aids, eating outside questionnaire

RecordTypes   consumption occasion, mean of consumption, quantified and described as eaten, recipes for self-made

FoodDescriptors   use foodex2 facets

3.4 ModelMath

Element	Type	Min. Ocurrences	Max. Ocurrences
Parameter	Parameter	1	*
QualityMeasures	QualityMeasures	0	1
ModelEquation	ModelEquation	0	1
FittingProcedure	string	0	1
Exposure	Exposure	0	1
Event	string	0	1

Chapter 4

DoseResponseModel

4.1 GeneralInformation

Element	Type	Min. Ocurrences	Max. Ocurrences
ModelName	string	1	1
Source	string	0	1
Identifier	string	0	1
Author	Contact	0	*
Creator	Contact	1	*
CreationDate	date	1	1
ModificationDate	date	0	*
Rights	string	1	1
Available	boolean	0	1
Format	string	0	1
Reference	Reference	0	*
Language	string	0	1
Software	string	0	1
LanguageWrittenIn	string	1	1
ModelCategory	ModelCategory	0	1
Status	string	0	1
Objective	string	0	1
Description	string	0	1

ModelName   Name given to the model.

Source   Related resource from which the described resource is derived.

Identifier   Unambiguous ID given to the model.

Author   Person who generated the model code originally.

Creator   Person or institution who contributed to the encoding of the model in its present form by creating the model file.

CreationDate   Temporal information on the model creation date.

ModificationDate   Temporal information on the last modification of the model.

Rights   Information on rights held in an over the resource.

Available Availability of model.

Format Form of the model (file extension).

Language Language of the resource (some data or reports can be available in French language for example).

Software Program in which the model has been implemented.

LanguageWrittenIn Language used to write the model, e.g. R or MatLab

Status Curation status of the model.

Objective Objective of the model.

Description General description of the model.

4.2 Scope

Element	Type	Min. Ocurrences	Max. Ocurrences
Hazard	string	1	*
PopulationGroup	PopulationGroup	0	*
GeneralComment	string	0	1
TemporalInformation	string	0	1
SpatialInformation	SpatialInformation	0	1

4.3 DataBackground

Element	Type	Min. Ocurrences	Max. Ocurrences
Study	Study	1	1
StudySample	StudySample	0	*
Laboratory	Laboratory	0	*
Assay	Assay	0	*

4.4 ModelMath

Element	Type	Min. Ocurrences	Max. Ocurrences
Parameter	Parameter	1	*
QualityMeasures	QualityMeasures	0	1
ModelEquation	ModelEquation	0	1
FittingProcedure	string	0	1
Exposure	Exposure	0	1
Event	string	0	1

.1 GenericModel

```xml
<?xml version="1.0" encoding="UTF-8" ?>
<Document xmlns="http://www.example.org/GenericModel1.0.3">
    <GenericModel xmlns="http://www.example.org/GenericModel1.0.3">
        <GeneralInformation>
            <Name>Toy Model for Testing Purposes</Name>
            <Source>
                UNPUBLISHED STUDIES (EXPERIMENTS-OBSERVATIONS): Studies
                and surveys
            </Source>
            <Identifier>Toy_Model_Generic_01</Identifier>
            <Author>
                <Title>Dr.</Title>
                <FamilyName>Romanov</FamilyName>
                <GivenName>Natalia</GivenName>
                <Email>black_widow@marvel.com</Email>
                <Telephone>030 12345</Telephone>
                <StreetAddress>Nahmitzer Damm 40</StreetAddress>
                <Country>Russian Federation</Country>
                <City>Berlin</City>
                <Region>Berlin-Brandenburg</Region>
                <Organization>SHIELD</Organization>
            </Author>
            <Creator>
                <Title>Dr.</Title>
                <FamilyName>Romanov</FamilyName>
                <GivenName>Natalia</GivenName>
                <Email>black_widow@marvel.com</Email>
                <Telephone>030 12345</Telephone>
                <StreetAddress>Nahmitzer Damm 40</StreetAddress>
                <Country>Russian Federation</Country>
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                <Region>Berlin-Brandenburg</Region>
                <Organization>SHIELD</Organization>
            </Creator>
            <Creator>
                <Title>Mr.</Title>
                <FamilyName>Parker</FamilyName>
                <GivenName>Peter</GivenName>
                <Email>peter@parker.com</Email>
                <Telephone>03301 1369158</Telephone>
                <StreetAddress>Am Kleinen Wannsee 16</StreetAddress>
                <Country>United States</Country>
                <City>Potsdam</City>
                <Region>Brandenburg</Region>
                <Organization>Parker Industries</Organization>
            </Creator>
            <CreationDate>2018-04-20</CreationDate>
            <Rights>Creative Commons Attribution-NonCommercial 4.0</Rights>
            <Format>.fskx</Format>
            <Reference>
                <IsReferenceDescription>true</IsReferenceDescription>
                <Type>PAMP</Type>
                <Date>3805-07-02</Date>
                <Doi>10.1111/risa.12758</Doi>
                <AuthorList>Jack Bauer, Kiefer Sutherland</AuthorList>
                <Title>Quantitative Risk Assessment of Norovirus Transmission
                    in Food Establishments: Evaluating the Impact of
                    Intervention Strategies and Food Employee Behavior on the
                    Risk Associated with Norovirus in Foods
                </Title>
                <Abstract>
                    This research looks at the work of Margaret C. Anderson,
                    the editor of the Little Review. The review published first
                    works by Sherwood Anderson, James Joyce, Wyndham Lewis,
                    and Ezra Pound. This research draws upon mostly primary
                    sources including memoirs, published letters, and a
```

complete collection of the Little Review. Most prior research on Anderson focuses on her connection to the famous writers and personalities that she published and associated with. This focus undermines her role as the dominant creative force behind one of the most influential little magazines published in the 20th Century. This case example shows how little magazine publishing is arguably a literary art.
</Abstract>
<Status>Accepted</Status>
<Website>https://nature.com</Website>
<Comment>publisher demands edits</Comment>
</Reference>
<Reference>
<IsReferenceDescription>true</IsReferenceDescription>
<Date>3805−07−07</Date>
<Doi>10.1002/jmv.21237</Doi>
<AuthorList>James Bond, Timothy Dalton</AuthorList>
<Title>Norwalk virus: How infectious is it?</Title>
<Abstract>This project involves discovering how the American Revolution was remembered during the nineteenth century. The goal is to show that the American Revolution was memorialized by the actions of the United States government during the 1800s. This has been done by examining events such as the Supreme Court cases of John Marshall and the Nullification Crisis. Upon examination of these events, it becomes clear that John Marshall and John Calhoun (creator of the Doctrine of Nullification) attempted to use the American Revolution to bolster their claims by citing speeches from Founding Fathers. Through showing that the American Revolution lives on in memory, this research highlights the importance of the revolution in shaping the actions of the United States government.
</Abstract>
<Status>Legal</Status>
<Website>www.sciencemag.org</Website>
<Comment>Publisher hates lettuce.</Comment>
</Reference>
<Reference>
<IsReferenceDescription>true</IsReferenceDescription>
<Type>DICT</Type>
<Date>3805−07−08</Date>
<Doi>10.1111/j.1539−6924.1999.tb01143.x</Doi>
<Title>Dose Response Models For Infectious Gastroenteritis</Title>
<Abstract>The purpose of this research is to identify a subtype of autism called Developmental Verbal Dyspraxia (DVD). DVD is a motor−speech problem, disabling oral−motor movements needed for speaking. The first phase of the project involves a screening interview where we identify DVD and Non−DVD kids. We also use home videos to validate answers on the screening interview. The final phase involves home visits where we use several assessments to confirm the child's diagnosis and examine the connection between manual and oral motor challenges. By identifying DVD as a subtype of Autism, we will eliminate the assumption that all Autistics have the same characteristics. This will allow for more individual consideration of Autistic people and may direct future research on the genetic factors in autism.
</Abstract>
<Status>Peer reviewed</Status>
<Website>http://www.techbriefs.com</Website>
<Comment>nerds</Comment>
</Reference>
<Language>English</Language>
<Software>R</Software>
<LanguageWrittenIn>R 3</LanguageWrittenIn>
<ModelCategory>
<ModelClass>Dose−response model</ModelClass>
<ModelClassComment>
This Model Class is very special
</ModelClassComment>

```xml
      </ModelCategory>
      <Status>Uncurated</Status>
      <Objective>Development of a dose−response models for Norwalk virus/
         norovirus</Objective>
      <Description>A norovirus dose response model is important for
         understanding its transmission and essential for development of a
         quantitative risk model. A new variant of the hit theory model of
         microbial infection was developed to estimate the variation in
         Norwalk virus infectivity, as well as the degree of virus aggregation,
         consistent with independent (electron microscopic) observations.
         Explicit modeling of viral aggregation was used to express virus
         infectivity per single infectious unit (particle). The hit theory
         model considers microbial infection as the result of a chain of
         conditional events: ingestion of one or more organisms from a
         Poisson−distributed suspension, followed by successful passage through
         any number of defensive barriers that may be present in the host.
         Individual organisms are thought to act independently, and any single
         surviving organism may reach an appropriate host cell and cause
         infection. Heterogeneity in the probability of individual organisms to
         achieve infection is modeled as a beta distribution. Illness is an
         important endpoint for risk assessment, especially for disease burden
         calculations. As illness is conditional on infection
         [Teunis et al.,1999], we wanted to study the probability of illness in
         infected subjects as a function of the applied dose. We used an
         existing model for illness dose response that is based on the concept
         of illness hazard during infection [Teunis et al., 1999].
      </Description>
   </GeneralInformation>

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   <Product>
      <Name>Lettuce</Name>
      <Description>fresh German lettuce</Description>
      <Unit>g</Unit>
      <Method>Organice production</Method>
      <Packaging>Packed</Packaging>
      <Treatment>Freezing</Treatment>
      <OriginCountry>Germany</OriginCountry>
      <OriginArea>Aachen, Kreisfreie Stadt</OriginArea>
      <FisheriesArea>Arctic Sea</FisheriesArea>
      <ProductionDate>3911−10−30</ProductionDate>
      <ExpiryDate>3911−12−01</ExpiryDate>
   </Product>
   <Product>
      <Name>Tomatoes</Name>
      <Description>not so fresh</Description>
      <Unit>g</Unit>
      <Method>Genetically modified</Method>
      <Packaging>Cardboard − paperboard</Packaging>
      <Treatment>Heating</Treatment>
      <OriginCountry>Spain</OriginCountry>
      <OriginArea>Lazio</OriginArea>
      <FisheriesArea>Mediterranean and Black Sea</FisheriesArea>
      <ProductionDate>3912−12−03</ProductionDate>
      <ExpiryDate>3913−02−01</ExpiryDate>
   </Product>
   <Product>
      <Name>
         ”Meat, preparations of meat, offals, blood, animal fats;
         fresh, chilled or frozen, salted, in brine, dried or
         smoked or processed as flours or meals; other processed
         products such as sausages and food preparations based on
         these
      </Name>
      <Description>
         Pretty much any processed meat product imaginable
      </Description>
      <Unit>g</Unit>
      <Method>Farmed domestic or cultivated</Method>
      <Packaging>Vacuum package</Packaging>
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```xml
        <Treatment>Fermentation</Treatment>
        <OriginCountry>United Kingdom</OriginCountry>
        <OriginArea>East Anglia</OriginArea>
        <FisheriesArea>Atlantic Ocean</FisheriesArea>
        <ProductionDate>3913-05-01</ProductionDate>
        <ExpiryDate>3914-05-01</ExpiryDate>
</Product>
<Hazard>
        <Type>Organic contaminants</Type>
        <Name>Norovirus (Norwalk-like virus)</Name>
        <Description>
            norovirus is described as nast and hard to get rid of
        </Description>
        <Unit>CFU</Unit>
        <AdverseEffect>morbitity</AdverseEffect>
        <SourceOfContamination>sewage</SourceOfContamination>
        <MaximumResidueLimit>0.01 mg/kg</MaximumResidueLimit>
        <NoObservedAdverseAffectLevel>
            10 mg
        </NoObservedAdverseAffectLevel>
        <LowestObservedAdverseAffectLevel>
            40 mg
        </LowestObservedAdverseAffectLevel>
        <AcceptableOperatorExposureLevel>
            50 mg
        </AcceptableOperatorExposureLevel>
        <AcuteReferenceDose>80 mg</AcuteReferenceDose>
        <AcceptableDailyIntake>20 mg</AcceptableDailyIntake>
</Hazard>
<Hazard>
        <Type>Microorganisms</Type>
        <Name>Salmonella Daarle</Name>
        <Description>
            we dont know how that got into the tomatoes but it is there
        </Description>
        <Unit>Fill</Unit>
        <AdverseEffect>mortality</AdverseEffect>
        <SourceOfContamination>air</SourceOfContamination>
        <MaximumResidueLimit>0.11 mg/kg</MaximumResidueLimit>
        <NoObservedAdverseAffectLevel>
            5 mg
        </NoObservedAdverseAffectLevel>
        <LowestObservedAdverseAffectLevel>
            50 mg
        </LowestObservedAdverseAffectLevel>
        <AcceptableOperatorExposureLevel>
            80 mg
        </AcceptableOperatorExposureLevel>
        <AcuteReferenceDose>100 mg</AcuteReferenceDose>
        <AcceptableDailyIntake>30 mg</AcceptableDailyIntake>
</Hazard>
<Hazard>
        <Type>Food additives</Type>
        <Name>Monoammonium glutamate</Name>
        <Description>tastes great but bad for your beach bod</Description>
        <Unit>fg/mL</Unit>
        <AdverseEffect>obesity</AdverseEffect>
        <SourceOfContamination>rodents</SourceOfContamination>
        <BenchmarkDose>123.12</BenchmarkDose>
        <MaximumResidueLimit>
            0.25 - 0.4 mg/kg
        </MaximumResidueLimit>
        <NoObservedAdverseAffectLevel>
            1 mg
        </NoObservedAdverseAffectLevel>
        <LowestObservedAdverseAffectLevel>
            100 mg
        </LowestObservedAdverseAffectLevel>
        <AcceptableOperatorExposureLevel>
            120 mg
```

```xml
            </AcceptableOperatorExposureLevel>
            <AcuteReferenceDose>140 mg</AcuteReferenceDose>
            <AcceptableDailyIntake>90 mg</AcceptableDailyIntake>
        </Hazard>
        <PopulationGroup>
            <Name>human consumer, no age specification</Name>
            <TargetPopulation>seniors</TargetPopulation>
            <PopulationDescription>
                80% are considered susceptible to infection
            </PopulationDescription>
            <PopulationGender>50% male</PopulationGender>
            <BMI>18.5 − 24.9</BMI>
            <SpecialDietGroups>love cake</SpecialDietGroups>
            <Region>Madrid</Region>
            <Country>Spain</Country>
            <PopulationRiskFactor>
                low physical activity
            </PopulationRiskFactor>
            <Season>spring</Season>
        </PopulationGroup>
        <PopulationGroup>
            <Name>human consumer, adult</Name>
            <TargetPopulation>soldiers</TargetPopulation>
            <PopulationDescription>highly vaccinated</PopulationDescription>
            <PopulationGender>90% male</PopulationGender>
            <BMI>18.5 − 24.9</BMI>
            <SpecialDietGroups>20% muslim</SpecialDietGroups>
            <Region>Mittelburgenland</Region>
            <Country>Austria</Country>
            <PopulationRiskFactor>bullet to the head</PopulationRiskFactor>
            <Season>summer</Season>
        </PopulationGroup>
        <PopulationGroup>
            <Name>human consumer, men</Name>
            <TargetPopulation>millenials</TargetPopulation>
            <PopulationDescription>
                they get sick all the time
            </PopulationDescription>
            <PopulationGender>100% male</PopulationGender>
            <BMI>18.5 −24.9</BMI>
            <SpecialDietGroups>30% vegetarians</SpecialDietGroups>
            <Region>Nottingham</Region>
            <Country>United Kingdom</Country>
            <PopulationRiskFactor>vaping</PopulationRiskFactor>
            <Season>winter</Season>
        </PopulationGroup>
        <GeneralComment>
            (General Comment) The Scope of this model is universal
        </GeneralComment>
        <TemporalInformation>1900 − 2000</TemporalInformation>
    </Scope>
    <DataBackground>
        <Study>
            <Identifier>Study_Generic_Sheet_1</Identifier>
            <Title>Quantitative Risk Assessment of Norovirus Transmission
                in Food Establishments: Evaluating the Impact of
                Intervention Strategies and Food Employee Behavior on the
                Risk Associated with Norovirus in Foods
            </Title>
            <Description>
                This Study will show, wether the FSK Lab will correctly
                read and run a generic and fully annotated model.
            </Description>
            <DesignType>Trial and Error</DesignType>
            <AssayMeasurementType>
                It works or it doesn't
            </AssayMeasurementType>
            <AssayTechnologyType>
                Anatomic−pathologic Tests
            </AssayTechnologyType>
```

```xml
        <AssayTechnologyPlatform>
            Orbital Platform
        </AssayTechnologyPlatform>
        <AccreditationProcedureForTheAssayTechnology>ISO/IEC17025
        </AccreditationProcedureForTheAssayTechnology>
        <ProtocolName>Extraction Protocol of FSK</ProtocolName>
        <ProtocolType>Extraction Protocol</ProtocolType>
        <ProtocolDescription>The protocol is definitely not made up
        </ProtocolDescription>
        <ProtocolURI>
            https://url−for−study−protocol-location.bfr.bund.de
        </ProtocolURI>
        <ProtocolVersion>version 1.0</ProtocolVersion>
        <ProtocolParametersName>Parameter 1</ProtocolParametersName>
        <ProtocolComponentsName>windows pc</ProtocolComponentsName>
        <ProtocolComponentsType>hardware</ProtocolComponentsType>
</Study>
<StudySample>
    <SampleName>Sample 1</SampleName>
    <ProtocolOfSampleCollection>
        SampleID_1
    </ProtocolOfSampleCollection>
    <SamplingStrategy>Convenient sampling</SamplingStrategy>
    <TypeOfSamplingProgram>Diet study</TypeOfSamplingProgram>
    <SamplingMethod>According to Reg 152/2009</SamplingMethod>
    <SamplingPlan>Random sampling</SamplingPlan>
    <SamplingWeight>
        description of the method employed to compute sampling
        weight (nonresponse−adjusted weight)
    </SamplingWeight>
    <SamplingSize>10000.0</SamplingSize>
    <LotSizeUnit>log10(CFU/25g)</LotSizeUnit>
    <SamplingPoint>Catering</SamplingPoint>
</StudySample>
<StudySample>
    <SampleName>Sample 2</SampleName>
    <ProtocolOfSampleCollection>
        SampleID_2
    </ProtocolOfSampleCollection>
    <SamplingStrategy>Selective sampling</SamplingStrategy>
    <TypeOfSamplingProgram>Monitoring</TypeOfSamplingProgram>
    <SamplingMethod>According to Reg 333/2007</SamplingMethod>
    <SamplingPlan>Stratified sampling</SamplingPlan>
    <SamplingWeight>
        description of the method employed to compute sampling
        weight (nonresponse−adjusted weight)
    </SamplingWeight>
    <SamplingSize>1000.0</SamplingSize>
    <LotSizeUnit>mL/kg</LotSizeUnit>
    <SamplingPoint>Air transport</SamplingPoint>
</StudySample>
<StudySample>
    <SampleName>Sample 3</SampleName>
    <ProtocolOfSampleCollection>SampleID_3
    </ProtocolOfSampleCollection>
    <SamplingStrategy>Census</SamplingStrategy>
    <TypeOfSamplingProgram>Control and eradication programmes
    </TypeOfSamplingProgram>
    <SamplingPlan>Multi−stage random sampling</SamplingPlan>
    <SamplingWeight>
        description of the method employed to compute sampling
        weight (nonresponse−adjusted weight)
    </SamplingWeight>
    <SamplingSize>2000.0</SamplingSize>
    <LotSizeUnit>mL/kg</LotSizeUnit>
    <SamplingPoint>Household</SamplingPoint>
</StudySample>
<DietaryAssessmentMethod>
    <CollectionTool>Food diaries</CollectionTool>
    <NumberOfNonConsecutiveOneDay>
```

```xml
            5
        </NumberOfNonConsecutiveOneDay>
        <SoftwareTool>FoodWorks</SoftwareTool>
        <RecordTypes>Mean of consumption</RecordTypes>
        <FoodDescriptors>(Beet) Sugar</FoodDescriptors>
    </DietaryAssessmentMethod>
    <DietaryAssessmentMethod>
        <CollectionTool>Other observational studies</CollectionTool>
        <NumberOfNonConsecutiveOneDay>
            10
        </NumberOfNonConsecutiveOneDay>
        <SoftwareTool>Nutritics</SoftwareTool>
        <RecordTypes>Quantified and described as eaten</RecordTypes>
        <FoodDescriptors>(Beet) Sugar</FoodDescriptors>
    </DietaryAssessmentMethod>
    <DietaryAssessmentMethod>
        <CollectionTool>Portion size measurement aids
        </CollectionTool>
        <NumberOfNonConsecutiveOneDay>20
        </NumberOfNonConsecutiveOneDay>
        <SoftwareTool>Purefood</SoftwareTool>
        <RecordTypes>Recipes for self−made</RecordTypes>
        <FoodDescriptors>(Beet) Sugar</FoodDescriptors>
    </DietaryAssessmentMethod>
    <Laboratory>
        <Accreditation>Accredited</Accreditation>
        <Name>National High Magnetic Field Laboratory</Name>
        <Country>United States</Country>
    </Laboratory>
    <Laboratory>
        <Accreditation>Everest Medical Laboratory</Accreditation>
        <Name>Everest Medical Laboratory</Name>
        <Country>India</Country>
    </Laboratory>
    <Assay>
        <Name>Bradford protein assay</Name>
        <Description>spectroscopic analytical procedure used to
            measure the concentration of protein in a solution. It is
            subjective, i.e., dependent on the amino acid composition
            of the measured protein
        </Description>
        <DetectionLimit>30−300</DetectionLimit>
        <QuantificationLimit>5000 − 8000</QuantificationLimit>
        <ContaminationRange>500−4000</ContaminationRange>
    </Assay>
    <Assay>
        <Name>ELISA</Name>
        <Description>ELISA is a popular format of \"wet−lab\" type
            analytic biochemistry assay that uses a solid−phase
            enzyme immunoassay (EIA) to detect the presence of a
            substance, usually an antigen, in a liquid sample or wet
            sample.
        </Description>
        <ContaminationRange>200−800</ContaminationRange>
    </Assay>
    <Assay>
        <Name>Plaque−Assay</Name>
        <Description>standard method used to determine virus
            concentration in terms of infectious dose. Viral plaque
            assays determine the number of plaque forming units (pfu)
            in a virus sample, which is one measure of virus quantity.
        </Description>
        <ContaminationRange>0.5 − 400</ContaminationRange>
    </Assay>
</DataBackground>
<ModelMath>
    <Parameter>
        <Id>Dose_matrix</Id>
        <Classification>input</Classification>
        <Name>Dose_matrix</Name>
```

```xml
        <Description>matrix with GEC NoV for each serving
            (rows=servings; columns = number of different
            employee−teams that prepare food)
        </Description>
        <Unit>Others</Unit>
        <UnitCategory>Other</UnitCategory>
        <DataType>matrixOfNumbers</DataType>
        <Source>Article</Source>
        <Subject>Animal</Subject>
        <Distribution>Bernoulli 1</Distribution>
        <Value>as.matrix(read.table(file =\"Dose_matrix.csv\",
            sep=\",\", header = TRUE, row.names=1))</Value>
        <VariabilitySubject>days</VariabilitySubject>
        <MinValue>10000.0</MinValue>
        <MaxValue>0.0</MaxValue>
        <Error>0.5</Error>
    </Parameter>
    <Parameter>
        <Id>nInf</Id>
        <Classification>output</Classification>
        <Name>nInf</Name>
        <Description>number of infected individuals, mean over stores
        (2000 servings per store)</Description>
        <Unit>Others</Unit>
        <UnitCategory>Other</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Batch of animals</Subject>
        <Distribution>Log−Logistic 2</Distribution>
        <VariabilitySubject>hours</VariabilitySubject>
        <MinValue>20000.0</MinValue>
        <MaxValue>0.1</MaxValue>
        <Error>0.4</Error>
    </Parameter>
    <Parameter>
        <Id>NIll</Id>
        <Classification>output</Classification>
        <Name>NIll</Name>
        <Description>number of ill individuals, mean over stores
            (2000 servings per store)</Description>
        <Unit>Others</Unit>
        <UnitCategory>Others</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Batch of products</Subject>
        <Distribution>Half Cauchy 1</Distribution>
        <MinValue>30000.0</MinValue>
        <MaxValue>0.3</MaxValue>
        <Error>0.3</Error>
    </Parameter>
    <Parameter>
        <Id>meanPos</Id>
        <Classification>output</Classification>
        <Name>prev18</Name>
        <Description>proportion of servings with >18 NoV</Description>
        <Unit>%</Unit>
        <UnitCategory>Arbitrary Fraction</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Other</Subject>
        <Distribution>Binomial 1</Distribution>
        <VariabilitySubject>weight</VariabilitySubject>
        <MinValue>50000.0</MinValue>
        <MaxValue>0.2</MaxValue>
        <Error>0.1</Error>
    </Parameter>
    <Parameter>
        <Id>prev18</Id>
        <Classification>output</Classification>
        <Name>prev18</Name>
```

```xml
        <Description>proportion of servings with >18 NoV</Description>
        <Unit>%</Unit>
        <UnitCategory>Arbitrary Fraction</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Other</Subject>
        <Distribution>Binomial 1</Distribution>
        <VariabilitySubject>weight</VariabilitySubject>
        <MinValue>50000.0</MinValue>
        <MaxValue>0.2</MaxValue>
        <Error>0.1</Error>
    </Parameter>
    <Parameter>
        <Id>prev100</Id>
        <Classification>output</Classification>
        <Name>prev100</Name>
        <Unit>%</Unit>
        <UnitCategory>Arbitrary Fraction</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Feces</Subject>
        <Distribution>Discrete distribution</Distribution>
        <VariabilitySubject>color</VariabilitySubject>
        <MinValue>60000.0</MinValue>
        <MaxValue>0.12</MaxValue>
        <Error>0.01</Error>
    </Parameter>
    <Parameter>
        <Id>prev1000</Id>
        <Classification>output</Classification>
        <Name>prev1000</Name>
        <Description>proportion of servings with >1000 Nov</Description>
        <Unit>%</Unit>
        <UnitCategory>Arbitrary Fraction</UnitCategory>
        <DataType>double</DataType>
        <Source>Model result</Source>
        <Subject>Feces</Subject>
        <Distribution>Geometric 1</Distribution>
        <VariabilitySubject>shape</VariabilitySubject>
        <MinValue>70000.0</MinValue>
        <MaxValue>0.142</MaxValue>
        <Error>0.02</Error>
    </Parameter>
    <Parameter>
        <Id>alpha</Id>
        <Classification>input</Classification>
        <Name>alpha</Name>
        <Description>Alpha parameter in dose response model related
            to probability of infection (shape of beta distribution)
        </Description>
        <Unit>Others</Unit>
        <UnitCategory>Other</UnitCategory>
        <DataType>double</DataType>
        <Source>Expert opinion</Source>
        <Subject>Carcass skin</Subject>
        <Distribution>Half−normal 1</Distribution>
        <Value>0.04</Value>
        <VariabilitySubject>age</VariabilitySubject>
        <MinValue>80000.0</MinValue>
        <MaxValue>0.01</MaxValue>
        <Error>0.03</Error>
    </Parameter>
    <Parameter>
        <Id>beta</Id>
        <Classification>input</Classification>
        <Name>beta</Name>
        <Description>Beta parameter in dose response model related to
            probability of infection (scale of beta distribution)
        </Description>
        <Unit>Others</Unit>
```

```xml
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Estimate</Source>
            <Subject>Product</Subject>
            <Distribution>Negative Binomial 1</Distribution>
            <Value>0.055</Value>
            <MinValue>900000.0</MinValue>
            <MaxValue>0.002</MaxValue>
            <Error>0.4</Error>
        </Parameter>
        <Parameter>
            <Id>eta</Id>
            <Classification>input</Classification>
            <Name>eta</Name>
            <Description>Eta parameter in dose response model related to
                probability of illnes (scale parameter for gamma distribution)
            </Description>
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Assumption</Source>
            <Subject>Package</Subject>
            <Distribution>Arcsine 2</Distribution>
            <Value>0.00255</Value>
            <VariabilitySubject>difficulty</VariabilitySubject>
            <MinValue>100000.0</MinValue>
            <MaxValue>0.01</MaxValue>
            <Error>0.5</Error>
        </Parameter>
        <Parameter>
            <Id>r</Id>
            <Classification>input</Classification>
            <Name>r</Name>
            <Description>
                R parameter in dose response model related to probability
                of illness (shape parameter for gamma distribution)
            </Description>
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Not applicable</Source>
            <Subject>Belly</Subject>
            <Distribution>Multivariate Gaussian 2</Distribution>
            <Value>0.086</Value>
            <VariabilitySubject>species</VariabilitySubject>
            <MinValue>110000.0</MinValue>
            <MaxValue>0.1</MaxValue>
            <Error>0.05</Error>
        </Parameter>
        <QualityMeasures>
            <SSE>0.0</SSE>
            <MSE>0.2</MSE>
            <RMSE>0.3</RMSE>
            <RSquared>0.9</RSquared>
            <AIC>0.0</AIC>
            <BIC>1.0</BIC>
        </QualityMeasures>
      </ModelMath>
    </GenericModel>
</Document>
```

.2   DoseResponseModel

Listing 2: Example of DoseResponseModel

```xml
<?xml version="1.0" encoding="UTF-8" ?>
<Document xmlns="http://www.example.org/GenericModel1.0.3">
    <DoseResponseModel>
```

```xml
<GeneralInformation>
    <ModelName>Toy Model for Testing Purposes</ModelName>
    <Source>UNPUBLISHED STUDIES (EXPERIMENTS-OBSERVATIONS): Studies and surveys</Source>
    <Identifier>Toy_Model_Generic_01</Identifier>
    <Author>
        <Title>Dr.</Title>
        <FamilyName>Romanov</FamilyName>
        <GivenName>Natalia</GivenName>
        <Email>black_widow@marvel.com</Email>
        <Telephone>030 12345</Telephone>
        <StreetAddress>Nahmitzer Damm 40</StreetAddress>
        <Country>Russian Federation</Country>
        <City>Berlin</City>
        <Region>Berlin-Brandenburg</Region>
        <Organization>SHIELD</Organization>
    </Author>
    <Creator>
        <Title>Dr.</Title>
        <FamilyName>Romanov</FamilyName>
        <GivenName>Natalia</GivenName>
        <Email>black_widow@marvel.com</Email>
        <Telephone>030 12345</Telephone>
        <StreetAddress>Nahmitzer Damm 40</StreetAddress>
        <Country>Russian Federation</Country>
        <City>Berlin</City>
        <Region>Berlin-Brandenburg</Region>
        <Organization>SHIELD</Organization>
    </Creator>
    <Creator>
        <Title>Mr.</Title>
        <FamilyName>Parker</FamilyName>
        <GivenName>Peter</GivenName>
        <Email>peter@parker.com</Email>
        <Telephone>03301 1369158</Telephone>
        <StreetAddress>Am Kleinen Wannsee 16</StreetAddress>
        <Country>United States</Country>
        <City>Potsdam</City>
        <Region>Brandenburg</Region>
        <Organization>Parker Industries</Organization>
    </Creator>
    <CreationDate>2018-04-20</CreationDate>
    <Rights>Creative Commons Attribution-NonCommercial 4.0</Rights>
    <Format>.fskx</Format>
    <Reference>
        <IsReferenceDescription>true</IsReferenceDescription>
        <Type>PAMP</Type>
        <Date>3805-07-02</Date>
        <Doi>10.1111/risa.12758</Doi>
        <AuthorList>Jack Bauer, Kiefer Sutherland</AuthorList>
        <Title>Quantitative Risk Assessment of Norovirus Transmission in Food Establishments: Evaluating the Impact
            of Intervention Strategies and Food Employee Behavior on the Risk Associated with Norovirus in Foods
        </Title>
        <Abstract>
            This research looks at the work of Margaret C. Anderson,
            the editor of the Little Review. The review published
            first works by Sherwood Anderson, James Joyce, Wyndham
            Lewis, and Ezra Pound. This research draws upon mostly
            primary sources including memoirs, published letters, and
            a complete collection of the Little Review. Most prior
            research on Anderson focuses on her connection to the
            famous writers and personalities that she published and
            associated with. This focus undermines her role as the
            dominant creative force behind one of the most influential
            little magazines published in the 20th Century. This case
            example shows how little magazine publishing is arguably a
            literary art
        </Abstract>
        <Status>Accepted</Status>
        <Website>https://nature.com</Website>
```

```xml
        <Comment>publisher demands edits</Comment>
    </Reference>
    <Reference>
        <IsReferenceDescription>true</IsReferenceDescription>
        <Date>3805−07−07</Date>
        <Doi>10.1002/jmv.21237</Doi>
        <AuthorList>James Bond, Timothy Dalton</AuthorList>
        <Title>Norwalk virus: How infectious is it?</Title>
        <Abstract>
            This project involves discovering how the American
            Revolution was remembered during the nineteenth century.
            The goal is to show that the American Revolution was
            memorialized by the actions of the United States
            government during the 1800s. This has been done by
            examining events such as the Supreme Court cases of John
            Marshall and the Nullification Crisis. Upon examination
            of these events, it becomes clear that John Marshall and
            John Calhoun (creator of the Doctrine of Nullification)
            attempted to use the American Revolution to bolster their
            claims by citing speeches from Founding Fathers. Through
            showing that the American Revolution lives on in memory,
            this research highlights the importance of the revolution
            in shaping the actions of the United States government.
        </Abstract>
        <Status>Legal</Status>
        <Website>www.sciencemag.org</Website>
        <Comment>Publisher hates lettuce.</Comment>
    </Reference>
    <Reference>
        <IsReferenceDescription>true</IsReferenceDescription>
        <Type>DICT</Type>
        <Date>3805−07−08</Date>
        <Doi>10.1111/j.1539−6924.1999.tb01143.x</Doi>
        <Title>Dose Response Models For Infectious Gastroenteritis</Title>
        <Abstract>
            The purpose of this research is to identify a subtype of
            autism called Developmental Verbal Dyspraxia (DVD). DVD is
            a motor−speech problem, disabling oral−motor movements
            needed for speaking. The first phase of the project involves
            a screening interview where we identify DVD and Non−DVD kids.
            We also use home videos to validate answers on the screening
            interview. The final phase involves home visits where we use
            several assessments to confirm the child's diagnosis and
            examine the connection between manual and oral motor
            challenges. By identifying DVD as a subtype of Autism, we will
            eliminate the assumption that all Autistics have the same
            characteristics. This will allow for more individual
            consideration of Autistic people and may direct future
            research on the genetic factors in autism.
        </Abstract>
        <Status>Peer reviewed</Status>
        <Website>http://www.techbriefs.com</Website>
        <Comment>nerds</Comment>
    </Reference>
    <Language>English</Language>
    <Software>R</Software>
    <LanguageWrittenIn>R 3</LanguageWrittenIn>
    <ModelCategory>
        <ModelClass>Dose−response model</ModelClass>
        <ModelClassComment>This Model Class is very special</ModelClassComment>
    </ModelCategory>
    <Status>Uncurated</Status>
    <Objective>Development of a dose−response models for Norwalk virus/ norovirus</Objective>
    <Description>A norovirus dose response model is important for understanding its transmission and essential
        for
        development of a quantitative risk model. A new variant of the hit theory model of microbial infection
        was
        developed to estimate the variation in Norwalk virus infectivity, as well as the degree of virus
        aggregation, consistent with independent (electron microscopic) observations. Explicit modeling of viral
        aggregation was used to express virus infectivity per single infectious unit (particle). The hit theory
```

model considers microbial infection as the result of a chain of conditional events: ingestion of one or more
organisms from a Poisson−distributed suspension, followed by successful passage through any number of defensive barriers that may be present in the host. Individual organisms are thought to act independently,
and any single surviving organism may reach an appropriate host cell and cause infection. Heterogeneity in
the probability of individual organisms to achieve infection is modeled as a beta distribution. Illness is
an important endpoint for risk assessment, especially for disease burden calculations. As illness is conditional on infection [Teunis et al.,1999], we wanted to study the probability of illness in infected subjects as a function of the applied dose. We used an existing model for illness dose response that is based on the concept of illness hazard during infection [Teunis et al., 1999].
</Description>
</GeneralInformation>

<Scope>
  <Hazard>
    <Type>Organic contaminants</Type>
    <Name>Norovirus (Norwalk−like virus)</Name>
    <Description>norovirus is described as nast and hard to get rid of</Description>
    <Unit>CFU</Unit>
    <AdverseEffect>morbitity</AdverseEffect>
    <SourceOfContamination>sewage</SourceOfContamination>
    <MaximumResidueLimit>0.01 mg/kg</MaximumResidueLimit>
    <NoObservedAdverseAffectLevel>10 mg</NoObservedAdverseAffectLevel>
    <LowestObservedAdverseAffectLevel>40 mg</LowestObservedAdverseAffectLevel>
    <AcceptableOperatorExposureLevel>50 mg</AcceptableOperatorExposureLevel>
    <AcuteReferenceDose>80 mg</AcuteReferenceDose>
    <AcceptableDailyIntake>20 mg</AcceptableDailyIntake>
  </Hazard>
  <Hazard>
    <Type>Microorganisms</Type>
    <Name>Salmonella Daarle</Name>
    <Description>we dont know how that got into the tomatoes but it is there</Description>
    <Unit>Fill</Unit>
    <AdverseEffect>mortality</AdverseEffect>
    <SourceOfContamination>air</SourceOfContamination>
    <MaximumResidueLimit>0.11 mg/kg</MaximumResidueLimit>
    <NoObservedAdverseAffectLevel>5 mg</NoObservedAdverseAffectLevel>
    <LowestObservedAdverseAffectLevel>50 mg</LowestObservedAdverseAffectLevel>
    <AcceptableOperatorExposureLevel>80 mg</AcceptableOperatorExposureLevel>
    <AcuteReferenceDose>100 mg</AcuteReferenceDose>
    <AcceptableDailyIntake>30 mg</AcceptableDailyIntake>
  </Hazard>
  <Hazard>
    <Type>Food additives</Type>
    <Name>Monoammonium glutamate</Name>
    <Description>tastes great but bad for your beach bod</Description>
    <Unit>fg/mL</Unit>
    <AdverseEffect>obesity</AdverseEffect>
    <SourceOfContamination>rodents</SourceOfContamination>
    <BenchmarkDose>123.12</BenchmarkDose>
    <MaximumResidueLimit>0.25 − 0.4 mg/kg</MaximumResidueLimit>
    <NoObservedAdverseAffectLevel>1 mg</NoObservedAdverseAffectLevel>
    <LowestObservedAdverseAffectLevel>100 mg</LowestObservedAdverseAffectLevel>
    <AcceptableOperatorExposureLevel>120 mg</AcceptableOperatorExposureLevel>
    <AcuteReferenceDose>140 mg</AcuteReferenceDose>
    <AcceptableDailyIntake>90 mg</AcceptableDailyIntake>
  </Hazard>
  <PopulationGroup>
    <Name>human consumer, no age specification</Name>
    <TargetPopulation>seniors</TargetPopulation>
    <PopulationDescription>80% are considered susceptible to infection</PopulationDescription>
    <PopulationGender>50% male</PopulationGender>
    <BMI>18.5 − 24.9</BMI>
    <SpecialDietGroups>love cake</SpecialDietGroups>
    <Region>Madrid</Region>
    <Country>Spain</Country>
    <PopulationRiskFactor>low physical activity</PopulationRiskFactor>

```xml
        <Season>spring</Season>
    </PopulationGroup>
    <PopulationGroup>
        <Name>human consumer, adult</Name>
        <TargetPopulation>soldiers</TargetPopulation>
        <PopulationDescription>highly vaccinated</PopulationDescription>
        <PopulationGender>90% male</PopulationGender>
        <BMI>18.5 − 24.9</BMI>
        <SpecialDietGroups>20% muslim</SpecialDietGroups>
        <Region>Mittelburgenland</Region>
        <Country>Austria</Country>
        <PopulationRiskFactor>bullet to the head</PopulationRiskFactor>
        <Season>summer</Season>
    </PopulationGroup>
    <PopulationGroup>
        <Name>human consumer, men</Name>
        <TargetPopulation>millenials</TargetPopulation>
        <PopulationDescription>they get sick all the time</PopulationDescription>
        <PopulationGender>100% male</PopulationGender>
        <BMI>18.5 −24.9</BMI>
        <SpecialDietGroups>30% vegetarians</SpecialDietGroups>
        <Region>Nottingham</Region>
        <Country>United Kingdom</Country>
        <PopulationRiskFactor>vaping</PopulationRiskFactor>
        <Season>winter</Season>
    </PopulationGroup>
    <GeneralComment>(General Comment) The Scope of this model is universal</GeneralComment>
    <TemporalInformation>1900 − 2000</TemporalInformation>
</Scope>
<DataBackground>
    <Study>
        <Identifier>Study_Generic_Sheet_1</Identifier>
        <Title>Quantitative Risk Assessment of Norovirus Transmission in Food Establishments: Evaluating the
            Impact
            of Intervention Strategies and Food Employee Behavior on the Risk Associated with Norovirus in Foods
        </Title>
        <Description>This Study will show, wether the FSK Lab will correctly read and run a generic and fully
            annotated model
        </Description>
        <DesignType>Trial and Error</DesignType>
        <AssayMeasurementType>It works or it doesn't</AssayMeasurementType>
        <AssayTechnologyType>Anatomic−pathologic Tests</AssayTechnologyType>
        <AssayTechnologyPlatform>Orbital Platform</AssayTechnologyPlatform>
        <AccreditationProcedureForTheAssayTechnology>ISO/IEC17025</AccreditationProcedureForTheAssayTechnology>
        <ProtocolName>Extraction Protocol of FSK</ProtocolName>
        <ProtocolType>Extraction Protocol</ProtocolType>
        <ProtocolDescription>The protocol is definitely not made up</ProtocolDescription>
        <ProtocolURI>https://url−for−study−protocol−location.bfr.bund.de</ProtocolURI>
        <ProtocolVersion>version 1.0</ProtocolVersion>
        <ProtocolParametersName>Parameter 1</ProtocolParametersName>
        <ProtocolComponentsName>windows pc</ProtocolComponentsName>
        <ProtocolComponentsType>hardware</ProtocolComponentsType>
    </Study>
    <StudySample>
        <SampleName>Sample 1</SampleName>
        <ProtocolOfSampleCollection>SampleID_1</ProtocolOfSampleCollection>
        <SamplingStrategy>Convenient sampling</SamplingStrategy>
        <TypeOfSamplingProgram>Diet study</TypeOfSamplingProgram>
        <SamplingMethod>According to Reg 152/2009</SamplingMethod>
        <SamplingPlan>Random sampling</SamplingPlan>
        <SamplingWeight>description of the method employed to compute sampling weight (nonresponse−adjusted
            weight)
        </SamplingWeight>
        <SamplingSize>10000.0</SamplingSize>
        <LotSizeUnit>log10(CFU/25g)</LotSizeUnit>
        <SamplingPoint>Catering</SamplingPoint>
    </StudySample>
    <StudySample>
        <SampleName>Sample 2</SampleName>
        <ProtocolOfSampleCollection>SampleID_2</ProtocolOfSampleCollection>
```

```xml
        <SamplingStrategy>Selective sampling</SamplingStrategy>
        <TypeOfSamplingProgram>Monitoring</TypeOfSamplingProgram>
        <SamplingMethod>According to Reg 333/2007</SamplingMethod>
        <SamplingPlan>Stratified sampling</SamplingPlan>
        <SamplingWeight>description of the method employed to compute sampling weight (nonresponse−adjusted
            weight)
        </SamplingWeight>
        <SamplingSize>1000.0</SamplingSize>
        <LotSizeUnit>uL/kg</LotSizeUnit>
        <SamplingPoint>Air transport</SamplingPoint>
    </StudySample>
    <StudySample>
        <SampleName>Sample 3</SampleName>
        <ProtocolOfSampleCollection>SampleID_3</ProtocolOfSampleCollection>
        <SamplingStrategy>Census</SamplingStrategy>
        <TypeOfSamplingProgram>Control and eradication programmes</TypeOfSamplingProgram>
        <SamplingPlan>Multi−stage random sampling</SamplingPlan>
        <SamplingWeight>description of the method employed to compute sampling weight (nonresponse−adjusted
            weight)
        </SamplingWeight>
        <SamplingSize>2000.0</SamplingSize>
        <LotSizeUnit>uL/kg</LotSizeUnit>
        <SamplingPoint>Household</SamplingPoint>
    </StudySample>
    <Laboratory>
        <Accreditation>Accredited</Accreditation>
        <Name>National High Magnetic Field Laboratory</Name>
        <Country>United States</Country>
    </Laboratory>
    <Laboratory>
        <Accreditation>Everest Medical Laboratory</Accreditation>
        <Name>Everest Medical Laboratory</Name>
        <Country>India</Country>
    </Laboratory>
    <Assay>
        <Name>Bradford protein assay</Name>
        <Description>spectroscopic analytical procedure used to measure the concentration of protein in a
            solution.
            It is subjective, i.e., dependent on the amino acid composition of the measured protein
        </Description>
        <DetectionLimit>30−300</DetectionLimit>
        <QuantificationLimit>5000 − 8000</QuantificationLimit>
        <ContaminationRange>500−4000</ContaminationRange>
    </Assay>
    <Assay>
        <Name>ELISA</Name>
        <Description>ELISA is a popular format of \"wet−lab\" type analytic biochemistry assay that uses a
            solid−phase enzyme immunoassay (EIA) to detect the presence of a substance, usually an antigen, in a
            liquid sample or wet sample.
        </Description>
        <ContaminationRange>200−800</ContaminationRange>
    </Assay>
    <Assay>
        <Name>Plaque−Assay</Name>
        <Description>standard method used to determine virus concentration in terms of infectious dose. Viral
            plaque
            assays determine the number of plaque forming units (pfu) in a virus sample, which is one measure of
            virus quantity.
        </Description>
        <ContaminationRange>0.5 − 400</ContaminationRange>
    </Assay>
</DataBackground>
<ModelMath>
    <Parameter>
        <Id>Dose_matrix</Id>
        <Classification>input</Classification>
        <Name>Dose_matrix</Name>
        <Description>matrix with GEC NoV for each serving (rows=servings; columns = number of different
            employee−teams that prepare food)
        </Description>
```

```xml
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>matrixOfNumbers</DataType>
            <Source>Article</Source>
            <Subject>Animal</Subject>
            <Distribution>Bernoulli 1</Distribution>
            <Value>as.matrix(read.table(file =\"Dose_matrix.csv\",sep=\",\", header = TRUE, row.names=1))</Value>
            <VariabilitySubject>days</VariabilitySubject>
            <MinValue>10000.0</MinValue>
            <MaxValue>0.0</MaxValue>
            <Error>0.5</Error>
        </Parameter>
        <Parameter>
            <Id>nInf</Id>
            <Classification>output</Classification>
            <Name>nInf</Name>
            <Description>number of infected individuals, mean over stores (2000 servings per store)</Description>
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Batch of animals</Subject>
            <Distribution>Log−Logistic 2</Distribution>
            <VariabilitySubject>hours</VariabilitySubject>
            <MinValue>20000.0</MinValue>
            <MaxValue>0.1</MaxValue>
            <Error>0.4</Error>
        </Parameter>
        <Parameter>
            <Id>NIll</Id>
            <Classification>output</Classification>
            <Name>NIll</Name>
            <Description>number of ill individuals, mean over stores (2000 servings per store)</Description>
            <Unit>Others</Unit>
            <UnitCategory>Others</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Batch of products</Subject>
            <Distribution>Half Cauchy 1</Distribution>
            <MinValue>30000.0</MinValue>
            <MaxValue>0.3</MaxValue>
            <Error>0.3</Error>
        </Parameter>
        <Parameter>
            <Id>meanPos</Id>
            <Classification>output</Classification>
            <Name>prev18</Name>
            <Description>proportion of servings with >18 NoV</Description>
            <Unit>%</Unit>
            <UnitCategory>Arbitrary Fraction</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Other</Subject>
            <Distribution>Binomial 1</Distribution>
            <VariabilitySubject>weight</VariabilitySubject>
            <MinValue>50000.0</MinValue>
            <MaxValue>0.2</MaxValue>
            <Error>0.1</Error>
        </Parameter>
        <Parameter>
            <Id>prev18</Id>
            <Classification>output</Classification>
            <Name>prev18</Name>
            <Description>proportion of servings with >18 NoV</Description>
            <Unit>%</Unit>
            <UnitCategory>Arbitrary Fraction</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Other</Subject>
            <Distribution>Binomial 1</Distribution>
```

```xml
            <VariabilitySubject>weight</VariabilitySubject>
            <MinValue>50000.0</MinValue>
            <MaxValue>0.2</MaxValue>
            <Error>0.1</Error>
    </Parameter>
    <Parameter>
            <Id>prev100</Id>
            <Classification>output</Classification>
            <Name>prev100</Name>
            <Unit>%</Unit>
            <UnitCategory>Arbitrary Fraction</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Feces</Subject>
            <Distribution>Discrete distribution</Distribution>
            <VariabilitySubject>color</VariabilitySubject>
            <MinValue>60000.0</MinValue>
            <MaxValue>0.12</MaxValue>
            <Error>0.01</Error>
    </Parameter>
    <Parameter>
            <Id>prev1000</Id>
            <Classification>output</Classification>
            <Name>prev1000</Name>
            <Description>proportion of servings with >1000 Nov</Description>
            <Unit>%</Unit>
            <UnitCategory>Arbitrary Fraction</UnitCategory>
            <DataType>double</DataType>
            <Source>Model result</Source>
            <Subject>Feces</Subject>
            <Distribution>Geometric 1</Distribution>
            <VariabilitySubject>shape</VariabilitySubject>
            <MinValue>70000.0</MinValue>
            <MaxValue>0.142</MaxValue>
            <Error>0.02</Error>
    </Parameter>
    <Parameter>
            <Id>alpha</Id>
            <Classification>input</Classification>
            <Name>alpha</Name>
            <Description>Alpha parameter in dose response model related to probability of infection (shape of beta
                distribution)
            </Description>
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Expert opinion</Source>
            <Subject>Carcass skin</Subject>
            <Distribution>Half−normal 1</Distribution>
            <Value>0.04</Value>
            <VariabilitySubject>age</VariabilitySubject>
            <MinValue>80000.0</MinValue>
            <MaxValue>0.01</MaxValue>
            <Error>0.03</Error>
    </Parameter>
    <Parameter>
            <Id>beta</Id>
            <Classification>input</Classification>
            <Name>beta</Name>
            <Description>Beta parameter in dose response model related to probability of infection (scale of beta
                distribution)
            </Description>
            <Unit>Others</Unit>
            <UnitCategory>Other</UnitCategory>
            <DataType>double</DataType>
            <Source>Estimate</Source>
            <Subject>Product</Subject>
            <Distribution>Negative Binomial 1</Distribution>
            <Value>0.055</Value>
            <MinValue>900000.0</MinValue>
```

```xml
                    <MaxValue>0.002</MaxValue>
                    <Error>0.4</Error>
                </Parameter>
                <Parameter>
                    <Id>eta</Id>
                    <Classification>input</Classification>
                    <Name>eta</Name>
                    <Description>Eta parameter in dose response model related to probability of illnes (scale parameter for
                        gamma distribution)
                    </Description>
                    <Unit>Others</Unit>
                    <UnitCategory>Other</UnitCategory>
                    <DataType>double</DataType>
                    <Source>Assumption</Source>
                    <Subject>Package</Subject>
                    <Distribution>Arcsine 2</Distribution>
                    <Value>0.00255</Value>
                    <VariabilitySubject>difficulty</VariabilitySubject>
                    <MinValue>100000.0</MinValue>
                    <MaxValue>0.01</MaxValue>
                    <Error>0.5</Error>
                </Parameter>
                <Parameter>
                    <Id>r</Id>
                    <Classification>input</Classification>
                    <Name>r</Name>
                    <Description>R parameter in dose response model related to probability of illness (shape parameter for
                        gamma
                        distribution)
                    </Description>
                    <Unit>Others</Unit>
                    <UnitCategory>Other</UnitCategory>
                    <DataType>double</DataType>
                    <Source>Not applicable</Source>
                    <Subject>Belly</Subject>
                    <Distribution>Multivariate Gaussian 2</Distribution>
                    <Value>0.086</Value>
                    <VariabilitySubject>species</VariabilitySubject>
                    <MinValue>110000.0</MinValue>
                    <MaxValue>0.1</MaxValue>
                    <Error>0.05</Error>
                </Parameter>
                <QualityMeasures>
                    <SSE>0.0</SSE>
                    <MSE>0.2</MSE>
                    <RMSE>0.3</RMSE>
                    <RSquared>0.9</RSquared>
                    <AIC>0.0</AIC>
                    <BIC>1.0</BIC>
                </QualityMeasures>
            </ModelMath>
        </DoseResponseModel>
</Document>
```

Appendix A

RAKIP 1.0.3

In FSKML the implementation of the metadata is based on EMF and the following simple EMF types:
* *EString* * *EBoolean* * *EDate* * *EInt*

A.1 General structure

Every RAKIP model involves four main metadata components: general information, scope, data background and model math. In FSKML a JSON object contains four key-value pairs with the classes described in this document.

Key	Class
generalInformation	GeneralInformation
scope	Scope
dataBackground	DataBackground
modelMath	ModelMath

This translate to a JSON object with these four attributes:

Listing A.1: Example of GeneralInformation

```
{
    "generalInformation" : {},
    "scope" : {},
    "dataBackground" : {},
    "modelMath" : {}
}
```

FSKML defines a number of metadata classes:

- Assay

- Contact

- DataBackground

- DietaryAssessmentMethod

- GeneralInformation

- Hazard

- Laboratory

- ModelCategory

- ModelMath

- Parameter

- ParameterClassification

- ParameterType

- PopulationGroup

- Product

- Reference

- PublicationType

- SpatialInformation

- Scope

- Study

- StudySample

A.2 Assay

Property	Type	Cardinality
assayName	EString	1..1
assayDescription	EString	0..1
percentageOfMoisture	EString	0..1
percentageOfFat	EString	0..1
limitOfDetection	EString	0..1
limitOfQuantification	EString	0..1
leftCensoredData	Estring	0..1
rangeOfContamination	EString	0..1
uncertaintyValue	EString	0..1

Listing A.2: Example of GeneralInformation

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Assay",
    "assayName" : "Bradford protein assay",
    "assayDescription" : "spectroscopic analytical procedure ...",
    "limitOfDetection" : "30−300",
    "limitOfQuantification" : "5000 − 8000",
    "rangeOfContamination" : "500−4000"
}
```

A.2.1 Mapping to RAKIP Assay

RAKIP	FSKML
Assay name	assayName
Assay description	assayDescription
Percentage of moisture	percentageOfMoisture
Percentage of fat	percentageOfFat
Limit of detection	limitOfDetection
Limit of quantification	limitOfQuantification
Left-censored data	leftCensoredData
Range of contamination	rangeOfContamination
Uncertainty value	uncertaintyValue

A.3 Contact

Property	Type	Cardinality
title	EString	0..1
familyName	EString	0..1
givenName	EString	0..1
email	EString	1..1
telephone	EString	0..1
streetAddress	EString	0..1
country	EString	0..1
city	EString	0..1
zipCode	EString	0..1
region	EString	0..1
timeZone	EString	0..1
gender	EString	0..1
note	EString	0..1
organization	EString	0..1

Listing A.3: Example of Contact

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Contact",
    "title" : "Dr.",
    "familyName" : "Romanov",
    "givenName" : "Natalia",
    "email" : "black_widow@marvel.com",
    "telephone" : "030 12345",
    "streetAddress" : "Nahmitzer Damm 40",
    "country" : "Russian Federation",
    "city" : "Berlin",
    "region" : "Berlin−Brandenburg",
    "organization" : "SHIELD"
}
```

A.4 DataBackground

Property	Type	Cardinality
study	Study	1
studySample	StudySample	0
dietaryAssessmentMethod	DietaryAssessmentMethod	0
laboratory	Laboratory	0
assay	Assay	0

Listing A.4: Example of DataBackground

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//DataBackground",
    "study" : { ... },
    "studysample" : [...],
    "dietaryassessmentmethod" : [...],
    "laboratory" : [...],
    "assay" : [...],
}
```

A.4.1 Mapping to RAKIP to DataBackground

RAKIP	FSKML
Study	study
Study Sample	studySample
Dietary assessment method	dietaryAssessmentMethod
Laboratory	laboratory
Assay	assay

A.5 DietaryAssessmentMethod

Property	Type	Cardinality
collectionTool	EString	0..1
numberOfNonConsecutiveOneDay	EString	0..1
softwareTool	EString	0..1
numberOfFoodItems	EString	0..1
recordTypes	EString	0..1
foodDescriptors	EString	0..1

Listing A.5: Example of DietaryAssessmentMethod

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//DietaryAssessmentMethod",
    "collectionTool" : "food diaries",
    "numberOfNonConsecutiveOneDay" : 5,
    "softwareTool" : "FoodWorks",
    "recordTypes" : "Mean of consumption",
    "foodDescriptors" : "(Beet) Sugar"
}
```

A.5.1 Mapping to RAKIP DietaryAssessmentMethod

RAKIP	FSKML
Methodological tool to collect data	collectionTool
Number of non-consecutive one-day	numberOfNonConsecutiveOneDay
Dietary software tool	softwareTool
Number of food items	numberOfFoodItems
Type of records	recordTypes
Food descriptors	foodDescriptors

A.6 GeneralInformation

Property	Type	Cardinality
name	EString	1..1
source	EString	0..1
identifier	EString	1..1
author	Contact	1
creators	Contact	0
creationDate	EDate	1..1
modificationDate	EDate	0
rights	EString	1..1
available	EBoolean	0..1
format	EString	0..1
reference	Reference	1
language	EString	0..1
software	EString	0..1
languageWrittenIn	EString	0..1
modelCategory	ModelCategory	0
status	EString	0..1
objective	EString	0..1
description	EString	0..1

Listing A.6: Example of GeneralInformation

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//GeneralInformation",
    "name" : "Toy Model for Testing Purposes",
    "source" : "UNPUBLISHED STUDIES (EXPERIMENTS−OBSERVATIONS): Studies and surveys",
    "identifier" : "Toy_Model_Generic_01",
    "creationDate" : "2018−04−20T00:00:00",
    "rights" : "Creative Commons Attribution−NonCommercial 4.0",
    "format" : ".fskx",
    "language" : "English",
    "software" : "R",
    "languageWrittenIn" : "R 3",
    "status" : "Uncurated",
    "objective" : "Development of a dose−response models for Norwalk virus/ norovirus",
    "description" : "A norovirus dose response model is important for ...",
    "modelCategory" : [...],
    "creators" : [...],
    "reference" : [...]
}
```

A.6.1 Mapping to RAKIP GeneralInformation

RAKIP	FSKML
Study/Data/Model name	name
Source	source
Identifier	identifier
Author	author
Creator	creators
Creation date	creationDate
Last modified date	modificationDate
Rights	rights
Availability	available
URL	
Format	format
Reference	reference
Language	language
Software	software
Language written in	languageWrittenIn
Model category	modelCategory
Status	status
Objective	objective
Description	description

A.7 Hazard

Property	Type	Cardinality
hazardType	EString	0..1
hazardName	EString	1..1
hazardDescription	EString	0..1
hazardUnit	EString	0..1
adverseEffect	EString	0..1
sourceOfContamination	EString	0..1
benchmarkDose	EString	0..1
maximumResidueLimit	EString	0..1
noObservedAdverseAffectLevel	EString	0..1
lowestObservedAdverseAffectLevel	EString	0..1
acceptableOperatorExposureLevel	EString	0..1
acuteReferenceDose	EString	0..1
acceptableDailyIntake	Estring	0..1
hazardIndSum	EString	0..1

Listing A.7: Example of Hazard

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Hazard",
    "hazardType" : "Organic contaminants",
    "hazardName" : "norovirus (Norwalk−like virus)",
    "hazardDescription" : "novovirus is described as nast and hard to get rid of",
    "hazardUnit" : "CFU",
    "adverseEffect" : "morbitity",
    "sourceOfContamination" : "sewage",
    "maximumResidueLimit" : "0.01 mg/kg",
    "noObservedAdverseAffectLevel" : "10 mg",
    "lowestObservedAdverseAffectLevel" : "40 mg",
    "acceptableOperatorExposureLevel" : "50 mg",
    "acuteReferenceDose" : "80 mg",
    "acceptableDailyIntake" : "20 mg"
}
```

A.7.1 Mapping to RAKIP Hazard

RAKIP	FSKML
Hazard type	hazardType
Hazard name	hazardName
Hazard description	hazardDescription
Hazard unit	hazardUnit
Adverse effect	adverseEffect
Source of contamination	sourceOfContamination
Benchmark Dose (BMD)	benchmarkDose
Maximum Residue Limit (MRL)	maximumResidueLimit
No Observed Adverse Effect Level (NOAEL)	noObservedAdverseAffectLevel
Lowest Observed Adverse Effect Level (LOAEL)	lowestObservedAdverseAffectLevel
Acceptabnle Operator Exposure Level (AOEL)	acceptableOperatorExposureLevel
Acute Reference Dose (ARfD)	acuteReferenceDose
Acceptable Daily Intake (ADI)	acceptableDailyIntake
Hazard ind/sum	hazardIndSum

A.8 Laboratory

Property	Type	Cardinality
laboratoryAccreditation	StringObject	0..1
laboratoryName	EString	0..1
laboratoryCountry	EString	0

Listing A.8: Example of Laboratory

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Laboratory",
    "laboratoryName" : "National High Magnetic Field Laboratory",
    "laboratoryCountry" : "United States",
    "laboratoryAccreditation" : [ {
        "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//StringObject",
        "value" : "Accredited"
    }]
}
```

A.8.1 Mapping to RAKIP Laboratory

RAKIP	FSKML
Laboratory accreditation	laboratoryAccreditation
Laboratory name	laboratoryName
Laboratory country	laboratoryCountry

A.9 ModelCategory

Property	Type	Cardinality
modelClass	EString	1
modelSubClass	StringObject	0
modelClassComment	EString	0..1
basicProcess	EString	0..1

Listing A.9: Example of Laboratory

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//ModelCategory",
    "modelClass" : "Dose−response model",
    "modelClassComment" : "This Model Class is very special"
}
```

A.9.1 Mapping to RAKIP ModelCategory

RAKIP	FSKML
Model class	modelClass
Model Sub-Class	modelSubClass
Model Class comment	modelClassComment
Basic process	basicProcess

A.10 ModelMath

Property	Type	Cardinality
parameter	Parameter	1
qualityMeasures	StringObject	0
modelEquation	ModelEquation	0
fittingProcedure	EString	0..1
exposure	Exposure	0
event	StringObject	0

Listing A.10: Example of ModelCategory

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//ModelMath",
    "parameter" : [...],
    "qualityMeasures" : [ {
        "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//StringObject",
        "value" : "{\"SSE\":0.0,\"MSE\":0.2,\"RMSE\":0.3,\"Rsquared\":0.9,\"AIC\":0.0,\"BIC\":1.0}"
    } ]
}
```

A.10.1 Mapping to RAKIP ModelMath

RAKIP	FSKML
Parameter / Factor / Input / Output / "Data column"	Parameter
Quality measures	qualityMeasures
Model equation	modelEquation
Fitting procedure	fittingProcedure
Exposure	exposure
Events	event

A.11 Parameter

Property	Type	Cardinality
parameterID	EString	1..1
parameterClassification	ParameterClassification	1..1
parameterName	EString	1..1
parameterDescription	EString	0..1
parameterUnit	EString	1..1
parameterUnitCategory	Estring	0..1
parameterDataType	ParameterType	1..1
parameterSource	EString	0..1
parameterSubject	EString	0..1
parameterDistribution	EString	0..1
parameterValue	EString	0..1
reference	Reference	0
parameterVariabilitySubject	EString	0..1
parameterValueMin	EString	0..1
parameterValueMax	EString	0..1
parameterError	EString	0..1

A.11.1 Mapping to RAKIP Parameter

RAKIP	FSKML
Parameter ID	parameterID
Parameter classification	parameterClassification
Parameter name	parameterName
Parameter description	parameterDescription
Parameter unit	parameterUnit
Parameter unit category	parameterUnitCategory
Parameter data type	parameterDataType
Parameter source	parameterSource
Parameter subject	parameterSubject
Parameter distribution	parameterDistribution
Parameter value	parameterValue
Parameter Reference	reference
Parameter variability subject	parameterVariabilitySubject
Parameter value min	parameterValueMin
Parameter value max	parameterValueMax
Parameter error	parameterError

A.12 ParameterClassification

Literal	Name	Value
null	null	-1
Constant	Constant	0
Input	Input	1
Output	Output	2

A.13 ParameterType

Property	Type	Cardinality
null	null	-1
Integer	Integer	0
Double	Double	1
Number	Number	2
Date	Date	3
File	File	4
Boolean	Boolean	5
Vector[number]	VectorOfNumbers	6
Vector[string]	VectorOfStrings	7
Matrix[number,number]	MatrixOfNumbers	8
Matrix[string,string]	MatrixOfStrings	9
Object	Object	10
Other	Other	11
String	String	12

Listing A.11: Example of Parameter

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Parameter",
    "parameterID" : "Dose_matrix",
    "parameterClassification" : "Input",
    "parameterName" : "Dose_matrix",
    "parameterDescription" : "matrix with GEC NoV ...",
    "parameterUnit" : "Others",
    "parameterUnitCategory" : "Other",
    "parameterDataType" : "Matrix[number,number]",
    "parameterSource" : "Article",
```

```
    "parameterSubject" : "Animal",
    "parameterDistribution" : "Bernoulli 1",
    "parameterValue" : "as.matrix(read.table(file =\"Dose_matrix.csv\"))",
    "parameterVariabilitySubject" : "days",
    "parameterValueMin" : "10000.0",
    "parameterValueMax" : "0.0",
    "parameterError" : "0.5"
}
```

A.14   PopulationGroup

Property	Type	Cardinality
populationName	EString	1..1
targetPopulation	EString	0..1
populationSpan	StringObject	0
populationDescription	StringObject	0
populationAge	StringObject	0
populationGender	EString	0..1
bmi	StringObject	0
specialDietGroups	StringObject	0
patternConsumption	StringObject	0
region	StringObject	0
country	StringObject	0
populationRiskFactor	StringObject	0
season	StringObject	0

Listing A.12: Example of PopulationGroup

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//PopulationGroup",
    "populationName" : "human consumer, no age specification",
    "targetPopulation" : "seniors",
    "populationGender" : "50% male ",
    "populationDescription" : [ {
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//StringObject",
    "value" : "80% are considered susceptible to infection"
}
```

A.14.1   Mapping of RAKIP PopulationGroup and FSKML PopulationGroup

RAKIP	FSKML
Population name	populationName
Target population	targetPopulation
Population Span (years)	populationSpan
Population description	populationDescription
Population age	populationAge
Population gender	populationGender
BMI	bmi
Special diet groups	specialDietGroups
Pattern consumption	patternConsumption
Region	region
Country	country
Risk and population factors	populationRiskFactor
Season	season

A.15   Product

Property	Type	Cardinality
productName	EString	1..1
productDescription	EString	0..1
productUnit	EString	1..1
productionMethod	EString	0..1
packaging	EString	0..1
productTreatment	EString	0..1
originCountry	EString	0..1
originArea	EString	0..1
fisheriesArea	EString	0..1
productionDate	EDate	0..1
expiryDate	EDate	0..1

Listing A.13: Example of Product

```
{
    "eClass" : "http://BfR/bund/de/knime/model/metadata_V1.0.3#//Product",
    "productName" : "Lettuce",
    "productDescription" : "fresh german lettuce",
    "productUnit" : "g",
    "productionMethod" : "Organic production",
    "packaging" : "Packed",
    "productTreatment" : "Freezing",
    "originCountry" : "Germany",
    "originArea" : "Aachen, Kreisfreie Stadt",
    "fisheriesArea" : "Arctic Sea",
    "productionDate" : "3911−10−30T00:00:00",
    "expiryDate" : "3911−12−01T00:00:00"
}
```

A.15.1   Mapping of RAKIP Product and FSKML Product

RAKIP	FSKML
Product/matrix name	productName
Product/matrix description	productDescription
Product/matrix unit	productUnit
Method of production	productionMethod
Packaging	packaging
Product treatment	productTreatment
Country of origin	originCountry
Area of origin	originArea
Fisheries area	fisheriesArea
Date of production	productionDate
Date of expiry	expiryDate

A.16   Reference

Property	Type	Cardinality
isReferenceDescription	EBoolean	1..1
publicationType	PublicationType	0..1
publicationDate	EDate	0..1
pmid	EString	0..1
doi	EString	0..1
authorList	EString	0..1
publicationTitle	EString	1..1
publicationAbstract	EString	0..1
publicationJournal	EString	0..1
publicationVolume	EInt	0..1
publicationIssue	EInt	0..1
publicationStatus	EString	0..1
publicationWebsite	EString	0..1
comment	EString	0..1

A.16.1   Mapping of RAKIP Reference and FSKML Reference

RAKIP	FSKML
$Is_r eference_d escription?$	isReferenceDescription
Publication type	publicationType
Publication year	publicationDate
PubMed ID	pmid
Publication DOI	doi
Publication Author List	authorList
Publication Title	publicationTitle
Publication Abstract	publicationAbstract
Publication Journal	publicationJournal
Publication Volume	publicationVolume
Publication Issue	publicationIssue
Publication Status	publicationStatus
Publication website	publicationWebsite
Comment	comment

A.17   PublicationType

Enumeration of publication types in FSKML taken from RIS.